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	Paragraph	**Documents**	**Generic**
C.2	**USABILITY ENGINEERING PROCESS for USER INTERFACE OF UNKNOWN PROVENANCE**		
C.2.1	USE SPECIFICATION		
	The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1. The MANUFACTURER shall store this USE SPECIFICATION **Compliance is checked by inspection of the USABILITY ENGINEERING FILE.**		M3, M3.1
C.2.2	* Review of POST-PRODUCTION information		
	The MANUFACTURER of the MEDICAL DEVICE with UOUP shall review available POST-PRODUCTION information including complaints and field reports for incidents or near incidents. All identified cases of USE ERROR that could result in a HAZARDOUS SITUATION or those cases where field information suggests HAZARDS or HAZARDOUS SITUATIONS that could have been caused by inadequate USABILITY shall be stored in the USABILITY ENGINEERING FILE and addressed in C.2.3 and C.2.4. **Compliance is checked by inspection of the USABILITY ENGINEERING FILE.**	H3 Post Market Surveillance	IDDoc 23916 IDDoc 17824 IDDoc 15453 VM3/COP/18
C.2.3	HAZARDS and HAZARDOUS SITUATIONS related to USABILITY		
	The MANUFACTURER shall review the RISK ANALYSIS of the MEDICAL DEVICE with UOUP and ensure that the HAZARDS and HAZARDOUS SITUATIONS associated with **Compliance is checked by inspection of the USABILITY ENGINEERING FILE.**	E3, E7, E11,E13	IDDoc 22375 IDDoc 7742 IDDoc 23884
C.2.4	RISK CONTROL		
C.2.5	RESIDUAL RISK evaluation		
	Based on any new information identified in performing steps C.2.3 and C.2.4, the MANUFACTURER shall re-evaluate the overall RESIDUAL RISK according to ISO 14971:2007, 6.4, and document the result in either the USABILITY ENGINEERING FILE or the RISK MANAGEMENT FILE. **Compliance is checked by inspection of the USABILITY ENGINEERING FILE or the RISK MANAGEMENT FILE.**	E3	E3

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5.1	**Subclause 5.1 – Prepare USE SPECIFICATION** The USABILITY ENGINEERING PROCESS as described in this standard begins by identifying the most important characteristics related to the use of the MEDICAL DEVICE. These characteristics are defined by the MANUFACTURER and are based on factors such as intended medical indication, intended PATIENT population and operating principle and are fundamental to the function of the MEDICAL DEVICE. This information is documented in the MEDICAL DEVICE USE SPECIFICATION. These attributes are fundamental design inputs for identifying the known and foreseeable HAZARDS and HAZARDOUS SITUATIONS related to the USER INTERFACE. The MEDICAL DEVICE USE SPECIFICATION is the foundation for defining the USER INTERFACE SPECIFICATION. The list of characteristics associated with the USE SPECIFICATION is a subset of the INTENDED USE as specified in ISO 14971. (intended medical indication) The intended medical indication can be very broad or quite narrow. It is important for the MANUFACTURER to clearly specify and indicate in the ACCOMPANYING DOCUMENTATION the intended medical indication. The USER needs to understand the intended medical indication in order to determine whether a given MEDICAL DEVICE is appropriate for the PATIENT at hand.		
	– * intended medical indication; NOTE 1 This can include conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.		F1
	intended PATIENT population; NOTE 2 This can include age group, weight range, health, or condition.		F1
	intended part of the body or type of tissue applied to or interacted with;		F1
	intended USER PROFILE;		
	USE ENVIRONMENT; and operating principle. NOTE 3 The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the ‘statement of intended use’. **Compliance is checked by inspection of the USABILITY ENGINEERING FILE.**		F1
	sterile or non-sterile,		O1
	single use or reusable (needing reprocessing between uses),		O1
	hospital use or home use		F5,F9
	ambulance use, in hospital transport or wall mounted,		F5,F9

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	general ward or operating theatre use,		F5,F9
	ambient lighting or noise levels; and		F5,F9
	ambulance use, in hospital transport or wall mounted,		F5,F9
	USER'S personal protective equipment.		D10
	Compliance is checked by inspection of the USABILITY ENGINEERING FILE.		
5.2	**Subclause 5.2 – Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS** **The characteristics related to SAFETY include those related to the USE SPECIFICATION and how the MEDICAL DEVICE is to be used (see ISO 14971:2007, C.2.1) including:**		
	whether the MEDICAL DEVICE is intended to be routinely cleaned and disinfected or cleaned and sterilized (see ISO 14971:2007, C.2.9);		O1, F5, F6
	whether the MEDICAL DEVICE is interpretative (see ISO 14971:2007, C.2.12);		F5
	whether use of the MEDICAL DEVICE requires special training (see ISO 14971:2007, C.2.26) or other information for SAFETY is provided in general (see ISO 14971:2007, C.2.27); and		F5, F6
	whether successful application of the MEDICAL DEVICE depends on human factors in general (see ISO 14971:2007, [C.2.29). This includes whether USE ERROR can be caused by the USER INTERFACE including:		F5
	connection TASKS,		
	displays,		F1, F4
	action menus,		
	or by the USE ENVIRONMENT.		
	To identify USER INTERFACE characteristics that could be related to SAFETY it can be helpful to break down top level functions into TASKS for the USER and functions for	Tasks ;	Functions

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	the MEDICAL DEVICE. One possible method for this is functional analysis. This list of TASK activities and corresponding MEDICAL DEVICE functions provides input to identification of both technical requirements to the MEDICAL DEVICE including its USER INTERFACE SPECIFICATION and to further analysis of USABILITY such as TASK analysis. Both these identified results can constitute or help identify further characteristics related to SAFETY.	

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5.3	Subclause 5.3 – Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS The MANUFACTURER is required to compile a list of anticipated HAZARDS and HAZARDOUS SITUATIONS associated with the use of a MEDICAL DEVICE as part of the RISK MANAGEMENT PROCESS as specified in ISO 14971. A HAZARD cannot result in HARM unless a PATIENT, USER or a third party is truly exposed to it (i.e. a HAZARDOUS SITUATION occurs). Figure E.1 from ISO 14971:2007 illustrates the concept of exposure and other aspects. Figure A.1 demonstrates the linkage between the concept of a USE ERROR as a cause for a resulting HAZARDOUS SITUATION and HARM (exposure to a HAZARD).	E3 E4 E5 E6 E10
5.4	Subclause 5.4 – Identify and describe HAZARD-RELATED USE SCENARIOS In identifying HAZARD-RELATED USE SCENARIOS, the MANUFACTURER should investigate not only specific TASKS that the MANUFACTURER intends the USER to perform, but also other TASKS and actions that the MANUFACTURER does not intend the USER to perform but are reasonably foreseeable.	Tasks
5.5	**Subclause 5.5 – Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION** MEDICAL DEVICES can have only a few or a very large number of HAZARD-RELATED USE SCENARIOS and especially in the latter case, it is important for MANUFACTURERS to focus their attention and resources on the USER INTERFACE elements that could have the most impact on USERS' interactions with the MEDICAL DEVICE. This requires that MANUFACTURERS develop a scheme to make this determination in order to select the HAZARD-RELATED USE SCENARIOS (i.e. which USE SCENARIOS to include in the SUMMATIVE EVALUATION). Selection of the HAZARD-RELATED USE SCENARIOS can be based on the SEVERITY of the potential consequences of the associated HAZARDS. It can be needed in this way to focus on HAZARDS rather than RISKS because the probability of occurrence of encountering a HAZARD, which is one component of RISK, can be very difficult to	**Hazards**

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	estimate, especially for a novel MEDICAL DEVICE for which no POST-PRODUCTION data are available. Another basis for selection of the HAZARD-RELATED USE SCENARIOS is the RISK of the occurrence of HARM to the PATIENT or USER. These values can also be difficult to determine, as they are based on assumptions closely related to probability of occurrence and without data, can be difficult to justify. Finally, and only in the presence of data that provides a justification, should RISK values based on the combination of SEVERITY and probability of occurrence of the HAZARD be used as the basis for prioritization of HAZARD-RELATED USE SCENARIOS. Values for these probabilities or probability of occurrence can be derived from POST-PRODUCTION data on current or previous versions of the same MEDICAL DEVICE or on the level of certainty that the RISK CONTROL measures are effective, which should also be justified with data. A more controversial approach to HAZARD-RELATED USE SCENARIO prioritization takes the effects of time into consideration. For example, IEC 60601-1-8:2006 and IEC 60601-1- 8:2006/AMD1:2012, Table 1, uses this approach. A similar approach could be taken for prioritizing TASKS for inclusion in USABILITY TESTING. This approach is similar to an estimation of RISK based on analysis of the sequence of events leading to HARM, by estimating components of probability using e.g. fault tree analysis.	

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5.6	**Subclause 5.6 – Establish USER INTERFACE SPECIFICATION** Based on the information collected in the preceding PROCESS steps, the USER INTERFACE SPECIFICATION contains the detailed and testable design requirements for the USER INTERFACE to ensure that the MEDICAL DEVICE that RISKS caused by USABILITY problems are acceptable. These requirements are MEDICAL DEVICE-function specific as they are based on the USE SPECIFICATION as well as the identified USE ERRORS and the HAZARD-RELATED USE SCENARIOS.	
5.7	**Subclause 5.7 – Establish USER INTERFACE EVALUATION plan** The MANUFACTURER should apply one or more methods for the USER INTERFACE EVALUATION. Findings based on any single method can be insufficient (e.g. simulated use might not be adequate to explore some HAZARD-RELATED USE SCENARIOS). This might require supplemental USER INTERFACE EVALUATION under conditions of actual use.	HAZARD-RELATED USE SCENARIOS
5.7.2	**Subclause 5.7.2 – FORMATIVE EVALUATION planning (criteria for determining when no further iterations are needed)** FORMATIVE EVALUATION of USABILITY including USABILITY TESTS typically does not have formal acceptance criteria. The purpose of these evaluations is to iterate the design of the USER INTERFACE to achieve a specified quality level and to increase the likelihood that the final SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE can be conducted successfully. The decision to stop iterating the USER INTERFACE design is based on the quality level being measured during the later stages of FORMATIVE EVALUATIONS. No further iterations are required when the quality level has been achieved that gives the MANUFACTURER the confidence that the final acceptance criteria will be met when the SUMMATIVE EVALUATION is conducted at the end of the iterative design cycle.	SUMMATIVE EVALUATION of the USABILITY
5.7.3	**Subclause 5.7.3 – SUMMATIVE EVALUATION planning d) (availability of the ACCOMPANYING DOCUMENTATION and provision of training)**	Historic evaluation of user experiences H1, H2, H3.1

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	ACCOMPANYING DOCUMENTATION is part of the MEDICAL DEVICE USER INTERFACE and should be available to the USER during the SUMMATIVE EVALUATION, as appropriate to simulate realistic use. SUMMATIVE EVALUATION is intended to simulate actual use with intended USERS. Its purpose is to evaluate the USABILITY of USER INTERFACE as it relates to the successful completion of the TASKS associated with HAZARD-RELATED USE SCENARIOS. For SUMMATIVE EVALUATION to be a realistic simulation of actual use, both the actual ACCOMPANYING DOCUMENTATION needs to be available to the USER and the USER needs to have received the expected training. If USER training is a RISK CONTROL measure and is expected prior to use, that training needs to be received and an appropriate elapsed time to accommodate for learning decay needs to occur. Since in this case the training is a RISK CONTROL measure, the SUMMATIVE EVALUATION cannot evaluate its 'effectiveness as a RISK CONTROL measure' if the training has not been delivered in a realistic manner. Similarly, the 'effectiveness as a RISK CONTROL measure' of the ACCOMPANYING DOCUMENTATION cannot be assessed if the ACCOMPANYING DOCUMENTATION is not available to the USER in a realistic manner. NOTE Effectiveness as a RISK CONTROL measure' relates to ISO 14971:2007, 6.3, and not to the defined term, EFFECTIVENESS.	Comments on Training Comments on Risk E1 Post market surveillance H3

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	e) (USABILITY TEST) SUMMATIVE EVALUATION of USABILITY has formal acceptance criteria. Documenting the criteria for determining whether the USER has successfully completed the TASKS associated with the HAZARD-RELATED USE SCENARIOS is required. These criteria correspond to the criteria for RISK acceptability as required in ISO 14971:2007, 3.4 d). Furthermore, these criteria need to be consistent with the MANUFACTURER'S policy for setting RISK acceptability criteria as required in ISO 14971:2007, 3.2. One possible way to express these criteria is that no USE ERROR that leads to HARM occurs. Another way is no USE ERROR leads to unacceptable RISK of HARM. Although USERS might not commit a USE ERROR while performing a TASK, they might have difficulty performing the TASK. A use difficulty could become a USE ERROR, which could lead to HARM. Use difficulties can appear in USABILITY TESTING, for example, as a USER hesitating, "exploring" the USER INTERFACE, unexpectedly referring to the ACCOMPANYING DOCUMENTATION BS EN 62366-1:2015 – 36 – IEC 62366-1:2015 ⏃ IEC 2015 before taking the correct action or commenting during the post-test interview that something was hard to do. Difficulties can result from USER confusion and might indicate USER INTERFACE features that have an increased potential to cause USE ERROR for different USERS or under different conditions of use. Sample use difficulties are listed below. – USER browses through many MEDICAL DEVICE display screens before finding the one enabling her to view a PATIENT monitor's alarm limits. – USER comments that the graduation marks on a pre-filled, glass syringe are difficult to read because the marks are thin lines with low contrast against the background surface. – USER struggles to open a package containing a sterile MEDICAL DEVICE, pulling on a tab with great force. Suddenly, the package tears open, almost causing the contents to spill out. – USER repeatedly presses a fluid tube into an air detector in an attempt to keep it in place. – USER comments that the display	

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	on an infusion pump has glare and is hard to read. Consequently, the USER struggles to identify the correct infusion rate but finally succeeds in setting the rate.	
5.8	**Subclause 5.8 – Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION** The design of the USER INTERFACE should be focused on the USER'S needs and requirements. A multidisciplinary team approach to USER INTERFACE design is required. This team can include actual USERS, engineers, USER-interface specialists, cognitive psychologists, multimedia programmers, USABILITY engineers, marketing and training personnel. The MANUFACTURER should conduct iterative USER INTERFACE design and development. USABILITY ENGINEERING, including FORMATIVE EVALUATION, should begin early and continue iteratively throughout the MEDICAL DEVICE design and development PROCESS.	**E7**