Kinepict Medical Imaging Tool Device Hazard Analysis

Version 1-001

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CE 0197

This product bears a CE marking in accordance with the provisions of the Council Directive 93/42/EEC of June 14th,1993 concerning medical devices. The CE marking applies only to medico-technical and medical products introduced in connection with the above mentioned comprehensive EC directives.

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Kinepict Medical Imaging Tool
Device Hazard Analysis

Introduction

The Device Hazard Analysis of the Kinepict Medical Imaging Tool strictly follows the rules of the EN ISO 14971:2012 standard. It *does contain*

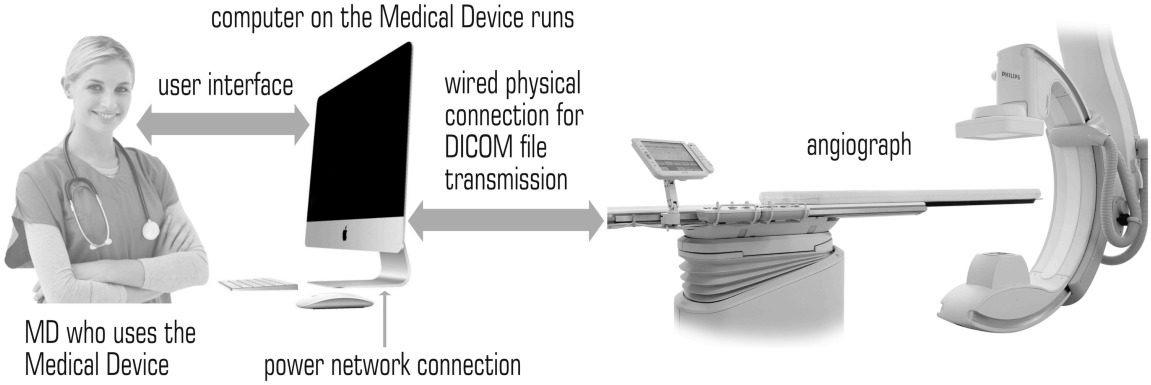
- the identification and listing of steps in the process where hazards of significance occur;
- the listing of all identified hazards and their significance associated with each step;
- the listing of all preventive measures to control each hazard.

The Device Hazard Analysis *does not contain* Hazard and Operability Study (HAZOP), Failure Mode and Effects Analysis (FMEA), and Fault Tree Analysis.

Contextual Environment

The Kinepict Medical Imaging Tool is a software program, runs on a desktop computer, connected to an angiograph getting DICOM files to enhance them by its DVA (Digital Variance Angiography) image generation as depicted below.

Kinepict Medical Imaging Tool as Medical Device
and its contextual environment



Preliminary Hazard Analysis (PHA)

Taking into consideration that the Kinepict Medical Imaging Tool as Medical Device

- *is not intended* to be in contact (i.e. surface contact, invasive contact, or implantation) with the patient and other persons;
- *there are no* materials and components are utilised in that;
- *does not deliver* energy to and extract from the patient;
- *does not deliver* substances to and extract from the patient;
- *does not process* biological materials for subsequent re-use, transfusion or transplantation;

- *is not supplied* sterile and intended to be sterilized by the user there are no other microbiological controls applicable;
- i*s not intended* to be routinely cleaned and disinfected by the user;
- *there are no* unwanted outputs of energy or substances from that;
- *does not influence* the environment;
- *cannot be associated* with essential consumables or accessories;
- *does not have* delayed or long-term use effects;
- *does not have* lifetime determinant factors;
- *is not intended* for single use;
- *does not need* safe decommissioning or disposal of that is necessary;
- *does not need* new manufacturing processes to be established and introduced;
- *does not use* alarm system;
- *does not hold* data critical to patient care;
- *is not intended* to be mobile and portable.

Instead of that the Kinepict Medical Imaging Tool as Medical Device

- is interpretative;
- is intended for use in conjunction with other medical device;
- is susceptible to environmental influences;
- does need maintenance regularly;
- does contain software;
- does depend on human factors critically.

Hazard Categories

The contextual environment provides classification over the hazard categories:

- *hardware errors* of the computer on the Kinepict Imaging Tool runs (immanent electronical failures, electrical power outage);
- *software errors* regarding Kinepict Medical Imaging Tool (including software installation, licence management, security exposures, inherent programming errors);
- *signal transmission problems* between the angiograph and the computer on the Kinepict Imaging Tool runs (unwanted cable detachment, unlocked connectors, broken wire by forced small deflection radius, manufactural fault, ageing);
- *inadequate use* of the Kinepict Imaging Tool (missing knowledge and/or praxis, using unknown functions, incorrect or improper use, reasonably foreseeable, deliberately misuse)
- *susceptibility to operational environmental influences* (psychological stress as limiting factor in proper use of the medical device, high level of illumination as constraining on computer screen readability, etc)

Detailed Risk Analysis and Mitigation Measures

Risks originated from Hardware Errors Hazard Category

Electric power outage

Risk Identifier:	R1
Estimated frequency / year:	5×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	Essential Electrical System (EES) Risk Category 1 (Critical Care Space), Type 1 EES is intended to used: having a minimum of two independent sources of electrical power – a normal source that generally supplies the entire facility and one or more alternate sources that supply power when the normal source is interrupted.

Total functional outage

Risk Identifier:	R2
Estimated frequency / year:	5×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in using desktop computers/operating systems from higher reliability class.

Very slow system responses (the computer suddenly slows down)

Risk Identifier:	R3
Estimated frequency / year:	5×10^{-1}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	Regular, substantial and deliberated hardware/software revisions have to be engaged regarding desktop computer.

Risks originated from Software Errors Hazard Category

Virus or other harmful infection

Risk Identifier:	R4
Estimated frequency / year:	2×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The document *Cyber Security* can serve with additional details.

Application crash (inherent programming errors)

Risk Identifier:	R5
Estimated frequency / year:	1×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss

Mitigation measures:	The introduced CMMI[1] Level 2 maximizes the software quality of the products from Kinepict Health Ltd minimizes the chances of the unwanted application crashes.

Licence expiring

Risk Identifier:	R6
Estimated frequency / year:	2×10^{-0}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	The customer care and management process of the Kinepict Health Ltd deals with the licence management in an exceptionally profound and thorough way.

Retarded operating system start on account of automatic software update

Risk Identifier:	R7
Estimated frequency / year:	2×10^{-0}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	Regular, substantial and deliberated software maintenance can preclude the unwanted automatic software updates and their consequences.

Installing an erroneous version of the Kinepict Medical Imaging Tools

Risk Identifier:	R8
Estimated frequency / year:	3×10^{-1}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	The introduced CMMI[1] Level 2 maximizes the software quality of the products from Kinepict Health Ltd minimizes the delivering of the erroneous software update packages.

Risks originated from Signal Transmission Problems Hazard Category

Unwanted cable detachment

Risk Identifier:	R9
Estimated frequency / year:	1×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in such essential cases.

Unlocked connectors

Risk Identifier:	R10
Estimated frequency / year:	1×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in such essential cases.

Broken wire by forced small defletion radius or by mechanical injury

Risk Identifier:	R11

[1] The Capability Maturity Model Integration (CMMI) is a process and behavioural model that helps organizations streamline process improvement and encourage productive, efficient behaviors that decrease risks in software, product and service development.

Estimated frequency / year:	1×10^{-1}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in such essential cases.

Manufactual fault of the cable

Risk Identifier:	R12
Estimated frequency / year:	5×10^{-2}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in using signal transmission cables from higher reliability class.

Ageing of the cable

Risk Identifier:	R13
Estimated frequency / year:	5×10^{-2}
Severity [1..11]:	3 (minor physical injury)
Functional dropout:	total functional loss
Mitigation measures:	The customer's local technical assistence staff is principally engaged in changing the aged signal transmission cables regularly.

Risks originated from Inadequate Use Hazard Category

Missing knowledge and/or praxis (e.g. user cannot start of a particular function)

Risk Identifier:	R14
Estimated frequency / year:	2×10^{-0}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	The customer care and management process of the Kinepict Health Ltd places great emphasis on virtual and real-life customer trainings.

Using unknown functions

Risk Identifier:	R15
Estimated frequency / year:	1×10^{-0}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	The customer care and management process of the Kinepict Health Ltd places great emphasis on virtual and real-life customer trainings.

Incorrect or improper general use

Risk Identifier:	R16
Estimated frequency / year:	1×10^{-0}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	The customer care and management process of the Kinepict Health Ltd places great emphasis on virtual and real-life customer trainings.

Reasonably foreseeable, deliberately misuse

Risk Identifier:	R17
Estimated frequency / year:	2×10^{-1}
Severity [1..11]:	2 (temporary impairment not requiring med. intervention)
Functional dropout:	temporal functional loss
Mitigation measures:	Strenghtened control of the personnel presence, hiring reliable staff.

Risks originated from Susceptibility to Operational Environmental Influences Hazard Category

Ambient temperaure is out of the computer's operating temperature range

Risk Identifier:	R18
Estimated frequency / year:	1×10^{-0}
Severity [1..11]:	1 (temporary discomfort)
Functional dropout:	temporal functional loss
Mitigation measures:	Eliminating of the heat source(s).

Air humidity endanger the computer

Risk Identifier:	R19
Estimated frequency / year:	5×10^{-2}
Severity [1..11]:	1 (temporary discomfort)
Functional dropout:	temporal functional loss
Mitigation measures:	Eliminating of the air umidity source(s).

Stray light of the intensive surgical lighting reduces the readability of the computer's screen

Risk Identifier:	R20
Estimated frequency / year:	1×10^{-0}
Severity [1..11]:	1 (temporary discomfort)
Functional dropout:	temporal functional loss
Mitigation measures:	Appropriate arragement of the computer.

Severity of the Resulting Harm[2]

11	Death
10	Life-threatening injury
9	Reduction in life expectancy
8	Irreversible deterioration of the state of health
7	Permanent impairment
6	Permanent damage to a body function/structure
5	Injury requiring medical intervention to prevent serious harm
4	Reversible deterioration of the state of health
3	Minor physical injury

[2] Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01), Annex H.2.5.4.3.

2	Temporary impairment not requiring medical intervention
1	Temporary discomfort

Risk Equivalence Classes

Severity	Estimated frequency / year			
	< 10^{-1}	**10^{-1} .. 10^{-2}**	**10^{-2} .. 10^{-3}**	**< 10^{-3}**
1	R18 R20		R19	
2	R6 R7 R14 R15 R16	R3 R8 R17		
3		R1 R2 R4 R5 R9 R10 R11	R12 R13	
4				
5				
6				
7				
8				
9				
10				
11				

Residual Risk Evaluation

Residual risk is the amount of risk that remains in the process after all the risks have been calculated, accounted and hedged. The *Risk Equivalence Classes* table does contain the residual risks already. Based on the above analysis, and in particular in view of the ISO 14971:2007(E) J.3 Disclosure, the Kinepict Health Ltd suggests to accept these risks.

Remarks

The primary medical device assures substantive visual control over the surgical treatment without using the Kinepict Medical Imaging Tool, as well. This is the reason why there are no more severe risk than 3 (minor physical injury) in the risk analysis.

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