



Risk Management File

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Revision History



Date	Version	Description of change	Author	Approved Name	Approved Date
08.11.2022	0.1	Initial version	Andrei Belski		
08.11.2022	1.0	Effective	Andrei Belski	Customer representative	08.11.2022

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Process Inputs



Description and identification of software that was analyzed	The software (healthcare application) is expected to assist patients with training their cognitive abilities by focusing on daily activities.
Scope of the hazard/risk analysis	Software Requirements Specification, Software Architecture Document
Regulatory classification	Class IIa
Responsible for the risk assessment process	Andrei Belski, compliance expert



Probability of hazard occurrence (P):

Probability of harm occurrence for a specific hazard or hazardous situation (value)		
Frequent	P5	Happens often
Probable	P4	Very likely to happen
Occasional	P3	May happen, but unlikely
Remote	P2	Rather unlikely to happen
Improbable	P1	Very unlikely to happen

The severity of the consequences of exposure to a hazard (S):

The severity of the harm (value)		
Catastrophic/Fatal	P5	Results in death
Critical	P4	Results in permanent impairment or irreversible injury
Serious/Major	P3	Results in injury or impairment requiring medical or surgical intervention
Minor	P2	Results in temporary injury or impairment not requiring medical or surgical intervention
Negligible	P1	Results in inconvenience or temporary discomfort

Risk Acceptance Criteria



The following risk evaluation criteria are used:

		Qualitative severity levels				
		Negligible	Minor	Serious/ Major	Critical	Catastrophic/ Fatal
Probability levels	Improbable	R1	R1	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Probable	R2	R2	R2	R2	R3
	Frequent	R2	R2	R3	R3	R3

RED – the risk must be taken into account and requires the development of a risk mitigation plan.

YELLOW – a residual risk; remains unacceptable even if the medical benefit outweighs the risk. It should be decided which information for safety is necessary to disclose. The risk requires a benefit analysis.

GREEN – the risk can be accepted at the current project phase and reevaluated during the next risk tracking step.



Risk ID		PR-1	PR-2
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Wrong report segregation	Data loss or corruption
	Cause	Data conversion errors	Network issues
	Hazardous situation	Wrong training progress	1. Loss of personal data 2. Loss of training progress 3. Inactive device 4. No user access
	Potential harm	Incorrect rehabilitation	Shortage of or no rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S1
	Harm occurrence probability (value)	P1	P3
	Risk value and risk acceptance criteria	R1	R2
	Are risk control measures required?	No	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	1. Platform SN (secured network platform) 2. Platform SN is properly configured 3. Platform SN resource monitoring 4. Data backup
	Traceability links	N/A	QA-1- S1.2 RR-12 RR-17
	Responsible person (risk owner)	N/A	Roman Tov
	Deadline / schedule	N/A	17-Dec-2022
	Status	N/A	Done

Hazard and Risk Analysis



Risk ID		PR-3
Hazard and harm identification	Software functional area	Data
	Potential hazard	New inputs not being stored after entering or editing
	Cause	Network issues
	Hazardous situation	1. Inability to add a new patient 2. Inability to select a VR device 3. Inability to assign a training plan
	Potential harm	No rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S1
	Harm occurrence probability (value)	P3
	Risk value and risk acceptance criteria	R2
	Are risk control measures required?	Yes
	Responsible person	Andrei Belski
	Date	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	1. Data retry (data is stored locally on the VR device. Once the Internet connection is available, the VR device sends data to the server) 2. Platform SN (secured network platform) 3. Platform SN is properly configured 4. Platform SN resource monitoring 5. Data
	Traceability links	QA-1- S1.2 QA3- S1 RR-12 RR-17
	Responsible person (risk owner)	Roman Tov
	Deadline / schedule	17-Dec-2022
	Status	Done



Risk ID		PR-4	PR-5	PR-6
Hazard and harm identification	Software functional area	Data	Data	Data
	Potential hazard	Time resynchronization	Time resynchronization	Display of erroneous clinical data
	Cause	Failure to resynchronize with the VR device	Failure to resynchronize with progress data	Malware
	Hazardous situation	Inactive device	No actual training progress	Wrong training progress
	Potential harm	Incorrect rehabilitation	Incorrect rehabilitation	Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S1	S2	S2
	Harm occurrence probability (value)	P1	P1	P2
	Risk value and risk acceptance criteria	R1	R1	R1
	Are risk control measures required?	No	No	No
	Responsible person	Andrei Belski	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	N/A	N/A
	Traceability links	N/A	N/A	N/A
	Responsible person (risk owner)	N/A	N/A	N/A
	Deadline / schedule	N/A	N/A	N/A
	Status	N/A	N/A	N/A



Risk ID		PR-7	PR-8
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Display of erroneous clinical data	Display of erroneous clinical data
	Cause	Code corruption	Network issues
	Hazardous situation	Wrong training progress	Wrong training progress
	Potential harm	Incorrect rehabilitation	Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S2
	Harm occurrence probability (value)	P1	P3
	Risk value and risk acceptance criteria	R1	R2
	Are risk control measures required?	No	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	1. Platform SN (secured network platform) 2. Platform SN is properly configured 3. Platform SN resource monitoring 4. Data backup
	Traceability links	N/A	QA-1- S1.2 RR-12 RR-17
	Responsible person (risk owner)	N/A	Roman Tov
	Deadline / schedule	N/A	17-Dec-2022
	Status	N/A	Done



Risk ID		PR-9	PR-10
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Display of erroneous clinical data	Data retrieval errors (e.g. wrong patient)
	Cause	Use of different browsers	Malware
	Hazardous situation	Wrong training progress	1. Loss of personal data 2. Loss of training progress
	Potential harm	Incorrect rehabilitation	1. No rehabilitation 2. Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S2
	Harm occurrence probability (value)	P3	P2
	Risk value and risk acceptance criteria	R2	R1
	Are risk control measures required?	Yes	No
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	1. Supported web-browsers: Microsoft Edge, Google Chrome, Safari 2. Supported resolutions: Desktop 1920x1080, Tablet 960x577 3. IFU/manual	N/A
	Traceability links	OE-1 OE-2	N/A
	Responsible person (risk owner)	Roman Tov	N/A
	Deadline / schedule	17-Dec-2022	N/A
	Status	Done	N/A



Risk ID		PR-11	PR-12
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Data retrieval errors (e.g. wrong patient)	Data retrieval errors (e.g. wrong patient)
	Cause	Code corruption	Unauthorized access
	Hazardous situation	1. Loss of personal data 2. Loss of training progress	1. Loss of personal data 2. Loss of training progress
	Potential harm	1. No rehabilitation 2. Incorrect rehabilitation	1. No rehabilitation 2. Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S2
	Harm occurrence probability (value)	P1	P2
	Risk value and risk acceptance criteria	R1	R2
	Are risk control measures required?	No	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	1. Keycloak IAM (identity access management) 2. Keycloak is properly configured (management of access roles and permissions) 3. Authorization
	Traceability links	N/A	QA- 1S1.1 RR-1 RR-4 RR-9 QA-1- S1.6 RR-2 RR-6 QA-1- S1.7 RR-3 RR-8
	Responsible person (risk owner)	N/A	Roman Tov
	Deadline / schedule	N/A	17-Dec-2022
	Status	N/A	Done



Risk ID		PR-13	PR-14
Hazard and harm identification	Software functional area	Data	Performance
	Potential hazard	Data retrieval errors (e.g. wrong patient)	Loss of connectivity
	Cause	Network issues	Network issues
	Hazardous situation	1. Loss of personal data 2. Loss of training progress	1. Unavailable personal data 2. Unavailable training progress 3. Inability to save training progress data
	Potential harm	1. No rehabilitation 2. Incorrect rehabilitation	Rehabilitation delay
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S1
	Harm occurrence probability (value)	P3	P3
	Risk value and risk acceptance criteria	R2	R2
	Are risk control measures required?	Yes	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	1. Platform SN (secured network platform) 2. Platform SN is properly configured 3. Platform SN resource monitoring 4. Data backup	1. Data retry (data is stored locally on the VR device; once the Internet connection is available, the VR device sends data to the server) 2. Platform SN (secured network platform) 3. Platform SN is properly configured 4. Platform SN resource monitoring 5. Data backup
	Traceability links	QA-1- S1.2 RR-12 RR-17	QA-1- S1.2 QA3- S1 RR-12 RR-17
	Responsible person (risk owner)	Roman Tov	Roman Tov
	Deadline / schedule	17-Dec-2022	17-Dec-2022
	Status	Done	Done



Risk ID		PR-15	PR-16
Hazard and harm identification	Software functional area	Performance	Performance
	Potential hazard	Software in an endless loop (frozen) on the network	Software in an endless loop (frozen) on the network
	Cause	DDoS attack	Code corruption
	Hazardous situation	1.Unavailable personal data 2. Unavailable training progress 3. Inability to save training progress data	1.Unavailable personal data 2. Unavailable training progress 3. Inability to save training progress data
	Potential harm	Rehabilitation delay	Rehabilitation delay
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S1	S1
	Harm occurrence probability (value)	P3	P1
	Risk value and risk acceptance criteria	R2	R1
	Are risk control measures required?	Yes	No
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	1. Platform SN (secured network platform) 2. Platform SN is properly configured 3. Platform SN resource monitoring	N/A
	Traceability links	QA-1- S1.2 RR-12 RR-17	N/A
	Responsible person (risk owner)	Roman Tov	N/A
	Deadline / schedule	17-Dec-2022	N/A
	Status	Done	N/A



Risk ID		PR-17	PR-18
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Data mishandling	Data mishandling
	Cause	Code corruption	Unauthorized access
	Hazardous situation	1. Loss of personal data 2. Loss of training progress	1. Loss of personal data 2. Loss of training progress
	Potential harm	1. No rehabilitation 2. Shortage of rehabilitation	1. No rehabilitation 2. Shortage of rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S1	S1
	Harm occurrence probability (value)	P1	P3
	Risk value and risk acceptance criteria	R1	R2
	Are risk control measures required?	No	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	1. Keycloak IAM (identity access management) 2. Keycloak is properly configured (management of access roles and permissions) 3. Authorization
	Traceability links	N/A	QA- 1S1.1 RR-1 RR-4 RR-9 QA-1- S1.6 RR-2 RR-6 QA-1- S1.7 RR-3 RR-8
	Responsible person (risk owner)	N/A	Roman Tov
	Deadline / schedule	N/A	17-Dec-2022
	Status	N/A	Done



Risk ID		PR-19	PR-20
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Data mishandling	Inadequate control of device status
	Cause	Malware	Code corruption
	Hazardous situation	1. Loss of personal data 2. Loss of training progress	Inability to save training progress data
	Potential harm	1. No rehabilitation 2. Shortage of rehabilitation	1. No rehabilitation 2. Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S1	S2
	Harm occurrence probability (value)	P2	P1
	Risk value and risk acceptance criteria	R1	R1
	Are risk control measures required?	No	Yes
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	N/A	N/A
	Traceability links	N/A	N/A
	Responsible person (risk owner)	N/A	N/A
	Deadline / schedule	N/A	N/A
	Status	N/A	N/A

Hazard and Risk Analysis



Risk ID		PR-21	PR-22
Hazard and harm identification	Software functional area	Data	Data
	Potential hazard	Inadequate control of device status	Inadequate control of device status
	Cause	Unauthorized access	Malware
	Hazardous situation	Inability to save training progress data	Inability to save training progress data
	Potential harm	1. No rehabilitation 2. Incorrect rehabilitation	1. No rehabilitation 2. Incorrect rehabilitation
Risk evaluation, ranking, analysis, and acceptance decision	Harm severity (value)	S2	S2
	Harm occurrence probability (value)	P3	P2
	Risk value and risk acceptance criteria	R2	R1
	Are risk control measures required?	Yes	No
	Responsible person	Andrei Belski	Andrei Belski
	Date	04-Nov-2022	04-Nov-2022
Risk control measures/risk treatment plan	Risk control measure	1. Keycloak IAM (identity access management) 2. Keycloak is properly configured (management of access roles and permissions) 3. Authorization	N/A
	Traceability links	QA- 1S1.1 RR-1 RR-4 QA-1- S1.6 RR-2 RR-6 QA-1- S1.7 RR-3 RR-8 RR-9	N/A
	Responsible person (risk owner)	Roman Tov	N/A
	Deadline / schedule	17-Dec-2022	N/A
	Status	Done	N/A

Residual Risk Evaluation



Risk ID	Residual risk evaluation result						Completeness of the risk control (recorded by the responsible person)				Overall residual risk evaluation (recorded by the responsible person)		
	Harm severity (value)	Harm occurrence probability (value)	Risk evaluation	Are there new hazards or hazardous situations?	Responsible person	Date	Responsible person	Status/conclusion	Date	Risks arising from risk control measures (risks from risks)	Responsible person	Status/conclusion	Date
PR-1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-2	S1	P2	R1	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-3	S1	P2	R1	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-8	S2	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-9	S2	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-11	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-12	S2	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-13	S2	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-14	S1	P2	R1	No	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-15	S1	P2	R1	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
PR-16	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-17	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-18	S1	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-19	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-21	S2	P2	R1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PR-22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A