Document control

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Document owner(s)	Department, title	Date	Version
E. Masih	*Biomechanical engineering, BSc*	*18-8-2024*	*Version 1*
G.J.M. Tuijthof	*Biomechanical engineering, Prof. Dr. Ir.*	*18-8-2024*	*Version 1*

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Document changes	Department, title	Date	Version	Summary of changes
E. Masih	*Biomechanical engineering, BSc*	*18-8-2024*	*Version 1.0*	*Final check*
G.J.M. Tuijthof	*Biomechanical engineering, Prof. Dr. Ir.*	*24-8-2025*	*Version 1*	*Update template according to ISO 14971:2019*
G.J.M. Tuijthof	*Biomechanical engineering, Prof. Dr. Ir.*	*10-9-2025*	*Version 1*	Final check Hazard and Hazard Traceability)

References

ISO 14971:2019

University of Twente
TechMed MDR Taskforce & Sustainable Healthcare Technology programme
Template name Hazard Traceability Matrix
Template number 5.01.3D Foot plate
Template version 1.0
Template date 210831

Risk Teams

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Team A		
Project team		
G.J.M. Tuijthof	*Prof. Dr. Ir.*	Project lead, mechanical engineer
E. Masih	*BSc*	Biomedical engineer

Team B
Expert team/use team

1. Make sure <u>at least</u> the following expertises (when relevant for you product) are in one of your risk teams
2. Make sure Risk Team members are, as much as possible, recruited from outside your project team

Possible Project Team Members
Depeartment Lead
Assistant Lead
Principal Investigator
Project Lead
Postdoc
PhD
Technician

Possible Expert Team Members
Medical physics
Electronics
Electromagnetism
Optics
Radiation
Mechanics
Thermal
Plastics
Plastic molding
Industrial design
User interface design
Software design
(Medical) Microbiology
Epidemiology
Toxicology
Health professional

Possible User Team Members
End user
Nurse
Health professional
Patient
Caretaker

Intended use and identification of characteristics related the safety of the medical device

Questions adapted from ISO/TR 24971:2020 Appendix A

No	Question	Applicable (Y/N/?)	Comment	Identified Hazard (see Worksheet Hazard Traceability column B)
1	What is the intended use and how is the medical device to be used?	Y	The indended use is to move and fixate the foot in a certain extreme position relative to the lower leg for a short period of time. (see 1.3D Footplate Device Classification.pdf)	
2	Is the medical device intended to be implanted?	N		
3	Is the medical device intended to be in contact with the patient or other persons?	Y	The foot and lower leg of the patient are in contact with the 3D Footplate	Bacteria
4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Y	Materials are compatible for skin contact	Inadequate performance of cleaning, disinfection or sterilization
5	Is energy delivered to or extracted from the patient?	Y	Load and displacement are offered to the patient's foot via the 3D Footplate by the medical professional in line with exertion of forces applied during manual clinical stress tests	bending/torsion
6	Are substances delivered to or extracted from the patient?	N		
7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	N		
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	N		
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	Y	The 3D Footplate should be cleaned for use with another patient	Inadequate performance of cleaning, disinfection or sterilization
10	Does the medical device modify the patient environment?	N		
11	Are measurements taken?	N		
12	Is the medical device interpretative?	N		
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	Y	The 3D Footplate was made compatible for imaging with radiography and CT-scanners	image artefacts
14	Are there unwanted outputs of energy or substances?	N		
15	Is the medical device susceptible to environmental influences?	N		
16	Does the medical device influence the environment?	N		
17	Does the medical device require consumables or accessories?	N		
18	Is maintenance or calibration necessary?	Y	Maintenance is necessary to confirm correct friction fixation forces and replace broken parts	in-service requirements (e.g. maintenance, reprocessing)
19	Does the medical device contain software?	N		
20	Does the medical device allow access to information?	N		
21	Does the medical device store data critical to patient care?	N		
22	Does the medical device have a restricted shelf-life?	Y	The fixation mechanism could deteriorate over time, and the lever of the clamp could break	Failure of a component due to ageing, wear or fatigue
23	Are there any delayed or long-term use effects?	N		
24	To what mechanical forces will the medical device be subjected?	Y	Friction forces to keep the rods fixated in a certain position; recation forces generated by the foot and lower leg of patient to keep enforced position	tension
25	What determines the lifetime of the medical device?	Y	Wear or ageing of materials, in particular, the fixation rod mechanism	Failure of a component due to ageing, wear or fatigue
26	Is the medical device intended for single use?	N		
27	Is safe decommissioning or disposal of the medical device necessary?	N		
28	Does installation or use of the medical device require special training or special skills?	Y	The amount of load to postion the foot in an extreme position should be the same as when applied in a clinical stress test, which can only be applied by medical professional that are trained execution of these test. So the use of the 3D Footplate does not require additional training.	Use by unskilled or untrained personnel
29	How will information for safety be provided?	Y	Instructions ifor use	Confusing or missing instructions for use
30	Are new manufacturing processes established or introduced?	N		
31	Is successful application of the medical device dependent on the usability of the user interface?	Y	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this 3D Footplate	Use by unskilled or untrained personnel
31,1	Can the user interface design features contribute to use error?	Y	In first time use positioning of the foot or leg might be misunderstood, also the need to fixate all 6 rods might be missed.	Complex or confusing control system Ambiguous or unclear state of the medical 3D Footplate
31,2	Is the medical device used in an environment where distractions can cause use error?	N		
31,3	Does the medical device have connecting parts or accessories?	N		
31,4	Does the medical device have a control interface?	N		
31,5	Does the medical device display information?	N		
31,6	Is the medical device controlled by a menu?	N		
31,7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?	Y	Positioning the foot in an extreme position and therby mimicking a clinical stress test is a critical performance measure to make use of this 3D Footplate	Use by unskilled or untrained personnel
31,8	Will the medical device be used by persons with special needs?	N		
31,9	Can the user interface be used to initiate unauthorised actions?	N		

32	Does the medical device include an alarm system?	N		
33	In what way(s) might the medical device be deliberately misused?	Y	Deliberately placing the foot in a wrong position or using other body parts such as the wrist in the same 3D Footplate	Confusing or missing instructions for use
34	Is the medical device intended to be mobile or portable?	Y	The 3D Footplate can be taken in and out of the imaging rooms	falling objects
35	Does the use of the medical device depend on essential performance?	Y	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this 3D Footplate	Slips, lapses and mistakes
36	Does the medical device have a degree of autonomy?	N		
37	Does the medical device produce an output that is used as an input in determining clinical action?	N		

Haz

	Risk analysis							Risk eval.	Risk control										Residual risk		
ID#	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	Notes	Occurrence	Severity	Criticality Index	Comment	Risk control measure	Rationale	Risk control measure	Risk control verification	Implemented (Y/N)	Occurrence	Severity	Criticality Index / Residual Has the risk been reduced ALAP? (Y/N)		Comment on residual risk	Possible failure cause	Benefit-Risk Analysis
	Energy hazards																				
	Acoustic energy																				
	infrasound							0									0				
	sound pressure							0									0				
	ultrasonic							0									0				
	Electric energy																				
	Electric fields							0									0				
	Leakage current							0									0				
	earth leakage							0									0				
	enclosure leakage							0									0				
	Magnetic fields							0									0				
	Static discharge							0									0				
	Voltage							0									0				
	Mechanical energy																				
	Kinetic energy							0									0				
Risk1	falling objects	(a)The 3D Footplate is portable and will be taken in and out the radiation rooms; (b) If the telescopic clamps are not closed and the 3D Footplate is tilted during transport, the foot plate with thin rods can slide off and fall to the ground	The 3D Footplate could fall and break	3D Footplate failure	No patient harm	3	2	6	3D Footplate is broken, needs to be replaced, which causes delays	Information for safety	No harm to patient; inconvenient for user	Include in user manual warning to close telescopic clamps before transport and not to tilt the 3D Footplate during transport	Check update user manual	Y	1	2	2	Y			There always remains a risk that the 3D Footplate is accidentally dropped, the documentation offers sufficient instructions to replace broken parts and checks to veriy correct functionality beofre use
	high pressure fluid injection							0									0				
Risk2	moving parts	Telescopic clamp fixation is insufficient causing the rods to move and with that the foot of the patients during use	Inadequate imaging	Additional radiation to the patient; 3D Footplate cannot perform its intended use	Imaging must be redone	3	3	9		Inherent safety by design	This risk refers to critical performance and needs to be mitigated	Ensure proper value of friction force generated by the telescopic clamp	The fixation friction is tested by pulling 60 N on each telescopic clamp assembly for 2 min	Y	1	3	3	Y	The clamps need to be calibrated	No calibration of the clamps will result in the friction force not being high enough	Calibration will be included in the assembly manual and this will likely ensure that calibration is performed accordingly.
	vibrating parts							0									0				
	Potential (stored) energy							0									0				
Risk3	bending/torsion	When fixated in the 3D Footplate and during imaging, the patient pulls on the 3D Footplate	The ground plate can bend and causing the patient to move the foot during imaging	3D Footplate cannot perform its intended use	No patient harm	3	2	6		Inherent safety by design	Although no harm to the patient will be done, this risk refers to critical performance and needs to be mitigated	Increase the resistance against bending or torsion by elongating the bottom plate	Usability testing where participant is asked whether they can move there foot when the rods are fixated	Y	1	3	3	Y	The ground plate can still bend a little	Movement by the patient	Instruction of the patient to keep still will resolve this risk, and therefore not influence the imaging
	compression							0									0				
	cutting, shearing							0									0				
	gravitational pull							0									0				
	suspended mass							0									0				
Risk4	tension	The foot is attached with Velcro straps for about 1 minute	- Cramp/pain in patient's foot; - A wound on the foot may be caused by friction of the Velcro straps	Harm to the patient's foot		4	2	8		Information for safety	The use of a towel will solve any issues no need for a redesign	Include in user manual to place a towel between the Velcro straps and the foot during use; Allow the Velcrostraps to be released with a few seconds by the user themselves	Quick release test by participants	Y	1	2	2	Y	The patient can still get cramps / pain, but can quickly released themselves the 3D Footplate	Pain /cramp in foot of patient	Due to rapid release of Velcro straps, patient can quickly deal with cramp
	Radiation energy																				
	Ionizing radiation							0									0				
	accelerated particles (alpha particles, electrons, protons, neutrons)							0									0				
	gamma							0									0				
	x-ray							0									0				

	Non-ionizing radiation							0								0				
	infrared							0								0				
	laser							0								0				
	microwave							0								0				
	ultraviolet							0								0				
	Thermal energy							0								0				
	Cryogenic effects							0								0				
	Hyperthermic effects							0								0				
	Biological and chemical hazards																			
Risk5	Bacteria	Use of the 3D Footplate without cleaning the 3D Footplate in between patients	Subsequent patient has open wounds in the lower extremity	Bacterial infection to patient		3	3	9		Information for safety	Medical professional will use the 3D Footplate, and they are used to clean medical 3D Footplate in between patient use and to check whether patients have wounds that may cause infection	Include in user manual that the 3D Footplate must be cleaned and maybe not be used on patients without open wounds of their lower extremity	Check update user manual	Y	1	3	3	Y	Cleaning protocol is not followed	Implement a cleaning log	Benefit of receiving a detailed diagnosis outweighs residual risk
	Fungi							0								0				
	Parasites							0								0				
	Prions							0								0				
Risk6	Toxins	Material of 3D Footplate can cause allergic reaction	3D Footplate in contact with patient's skin causes an allergic reaction	Allergic reaction patient		3	3	9		Inherent safety by design	Selection of biocompatible material in contact with patient	Polypropylene was chosen for its biocompatibility and easy to clean	Check bill of materials	Y	1	3	3	Y	Cleaning protocol is not followed	Implement a cleaning log	Benefit of receiving a detailed diagnosis outweighs residual risk
	Viruses							0								0				
	Chemical agents																			
	Carcinogenic, mutagenic, reproductive							0								0				
	Caustic, corrosive							0								0				
	acidic							0								0				
	alkaline							0								0				
	oxidants							0								0				
	Flammable, combustible, explosive							0								0				
	Fumes, vapours							0								0				
	Osmotic							0								0				
	Particles (including micro- and nanoparticles)							0								0				
	Pyrogenic							0								0				
	Solvents							0								0				
	Toxic							0								0				
	asbestos							0								0				
	heavy metals							0								0				
	inorganic toxicants							0								0				
	organic toxicants							0								0				
	silica							0								0				
	Immunological agents																			
	Allergenic							0								0				
	antiseptic substances							0								0				
	latex							0								0				
	Immunosuppressive							0								0				
	Irritants							0								0				
	cleaning residues							0								0				
	Sensitizing							0								0				
	Performance-related hazards																			
	Data							0								0				
	access							0								0				
	availability							0								0				
	confidentiality							0								0				
	transfer							0								0				
	integrity							0								0				
	Delivery							0								0				
	quantity							0								0				
	rate							0								0				
	Diagnostic information							0								0				
	examination result							0								0				

Risk7	image artefacts	During medical imaging the 3D Footplate is used attached to a patient	Medical images are unusable due to (metal or motion) artifacts	Additional radiation to the patient	Imaging must be redone	4	3	12		Inherent safety by design	This risk refers to critical performance and needs to be mitigated	Selection of material that does not cause image artefacts, and increase stiffness of ground plate to reduce motion of patient's foot	Make medical images and verify no metal artefacts; Usability testing where participant is asked whether they can move there foot when the rods are fixated	Y	1	3	3	Y	The ground plate can still bend a little	Movement by the patient	Instruction of the patient to keep still will resolve this risk, and therefore not influence the imaging
	image orientation							0									0				
	image resolution							0									0				
	patient identity / information							0									0				
	Functionality							0									0				
	alarm							0									0				
	critical performance							0									0				
	measurement							0									0				
	Requirements																				
	Inadequate specification of:																				
	design parameters							0									0				
	operating parameters							0									0				
	performance requirements							0									0				
Risk8	in-service requirements (e.g. maintenance, reprocessing)	Repeatedly use the product, especially repeated use of telescopic clamps, cause improper fixation causing the rods to move and with that the foot of the patients during use	Wear on clamps / rods and/or insufficient fixation causing inadequate imaging	Additional radiation to the patient; 3D Footplate cannot perform its intended use	Imaging must be redone	3	3	9		Information for safety	referring to risks 2 and 7, where inherent safety by design already has been executed. the 3D Footplate can offer sufficient friction forces also in case of wear	Ensure proper value of friction force generated by the telescopic clamp	The fixation friction is tested by pulling 60 N on each telescopic clamp assembly for 2 min	Y	1	3	3	Y	The clamps need to be calibrated	No calibration of the clamps will result in the friction force not being high enough	Calibration will be included in the assembly manual and this will likely ensure that calibration is performed accordingly.
	end of life							0									0				
	Manufacturing processes																				
	Insufficient control of:																				
Risk9	manufacturing processes	3D Footplate assembly	Inconsistent manufacturing process; Wrong materials used, wrong dimensions; wrong order of assembly; mistakes during assembly	3D Footplate cannot perform its intended use	No patient harm	5	2	10		Inherently safety by design	Design has been updated for easy manufacturing and assembly	The design is such that off-the-shelf components can be purchased and that some parts need to be 3Dprinted and laser cut; Assembly manual is provided that consist of IKEA-style instructions that are easy to follow by anyone and only require a hammer and a screwdriver	Assembly manual is verified for ease of use and avoidance of errors	Y	3	2	6	Y	The assembly manual reduces the chance that production errors are made. Off-the-shelve components are used that are not medical certified and 3D printing and laser cutting can be done in workshops that do not work under the ISO13485	Product fails before use on patients	Include warning in assembly manual that only qualified and trained professionals should manufacture the 3D Footplate; and that a thorough incoming goods inspection should take place for ordered off-the-shelf components
	changes to manufacturing processes							0									0				
Risk10	materials	3D Footplate is insufficiently strong and/or stiff	Parts can break or bend causing product to fail its intended use	3D Footplate cannot perform its intended use	No patient harm	4	2	8		Inherently safety by design	Weakest parts are identified which are the telescopic clamps and grounds plate	Ground plate is made stiffer by increasing cross large; telescopic clamps used be printed with an state-of-the-art FDM 3D printer to increase their strength	Design verification	Y	1	2	2	Y	Telescopic clamps still can break; The ground plate can still bend a little	Movement by the patient	Calibration instruction of the clamps helps reduce overloading; Instruction of the patient to keep still will resolve this item, and therefore not influence the imaging
	materials compatibility information							0									0				
	subcontractors							0									0				
	Transport and storage																				
	Inadequate packaging							0									0				
	Contamination or deterioration							0									0				
Risk11	Inappropriate storage and environmental conditions	3D Footplate stored under high temperature / high humidity	Accelerated degradation of materials especially the plastics	3D Footplate failure	No patient harm	3	2	6		Information for safety		Use appropriate symbols from ISO 7000, ISO 15223		Y	1	2	2	Y	The risk of storage damage has decreased due to use of correct symbols		
	Environmental factors																				
	Physical factors (e.g. heat, pressure, time)							0									0				
	Chemical factors (e.g. corrosion, degradation, contamination)							0									0				
	Electromagnetic fields (e.g. susceptibility to electromagnetic disturbance)							0									0				
	Inadequate supply of power							0									0				
	Inadequate supply of coolant							0									0				

	Cleaning, disinfection and sterilization																			
	Lack of validated procedures							0									0				
	Inadequate specification of requirements							0									0				
Risk12	Inadequate performance of cleaning, disinfection or sterilization	3D Footplate must be cleaned prior to a new patient in a proper manner	- Bacterial infection in patient - Without proper cleaning, damage to the product can occur	Harm to patient, 3D Footplate failure		4	2	8		Information for safety		Include in the user manual instruction that the needs to be cleaned 3D Footplate before and after use of a new patient.	Check update user manual	Y	1	2	2	Y	Cleaning protocol is not followed	Implement a cleaning log	Benefit of receiving a detailed diagnosis outweighs residual risk
								0									0				
	Disposal and scrapping																				
	No or inadequate information provided							0									0				
	Use error							0									0				
	Formulation																				
	Biodegradation							0									0				
	Biocompatibility							0									0				
	No information or inadequate specification provided							0									0				
	Incorrect formulations							0									0				
	Use error							0									0				
	Usability																				
Risk13	Confusing or missing instructions for use	There are two types of clamps	The user tries to use turn screws of the clamps for fixtion instead of the levers	3D Footplate failure		4	1	4		Information for safety		Include in user manual, the telescopic clamp levers are green-coloured to stand out	Check update user manual	Y	2	1	2				
Risk14	Complex or confusing control system	Not clear how to fixate the 3D Footplate; Forget to clamp all levers	Inadequate imaging	Additional radiation to the patient; 3D Footplate cannot perform its intended use	Imaging must be redone	3	3	9		Inherent safety design		The telescopic clamp levers are green-coloured to stand out	It will be tested during the usability tests	Y	1	3	3	Y	Medical professional can be distracted during fixation; label all clamps with a number		Demonstrated that 3D Footplate is easy to use
	Ambiguous or unclear state of the medical 3D Footplate							0									0				
	Ambiguous or unclear presentation of settings, measurements or other information							0									0				
	Misrepresentation of results							0									0				
	Insufficient visibility, audibility or tactility							0									0				
	Poor mapping of controls to actions, or of displayed information to actual state							0									0				
	Controversial modes or mapping as compared to existing equipment							0									0				
Risk15	Use by unskilled or untrained personnel	Only medical professional trained in executing manual clinical stress tests are allowed to use the 3D Footplate	- Damage of ligaments - Compromised results	Harm to the patient; Additional radiation to the patient		4	4	16		Information for safety	You need an imaging modality to effectively use the 3D Footplate, which is only available in a hospital setting with restricted access	Include in user manual clear warning and intended use	Check update user manual	Y	1	4	4	Y	Unauthorized people can still have access to the 3D Footplate	Unauthorized people can use the 3D Footplate	Since the 3D Footplate will be used in medical settings, use by other than medical professionals will likely not happen.
Risk16	Insufficient warning of side effects	Straps may cause wounds on the foot	if straps are pulled too tight, friction will occur and cause wounds	Harm to the patient		3	2	6		Information for safety	Only medical professional trained in executing manual clinical stress tests are allowed to use the 3D Footplate	Include instruction in user manual regarding the use of a towel can be used between the patient's skin and the straps	Check update user manual	Y	2	2	4	Y	Medical professional can be distracted		

Risk17	Insufficient warning of side effects	Overstressing the foot	Ligaments may be elongated or even damaged	Harm to the patient		3	3	9		Information for safety	Only medical professional trained in executing manual clinical stress tests are allowed to use the 3D Footplate	Include in user manual clear warning and intended use	Check update user manual	N	1	3	3	Y	Unauthorized people can still have access to the 3D Footplate	Unauthorized people can use the 3D Footplate	Since the 3D Footplate will be used in medical settings, use by other than medical professionals will likely not happen.
	Inadequate warning of hazards associated with re-use of single-use medical 3D Footplates							0									0				
	Incorrect measurement and other metrological aspects							0									0				
	Incompatibility with consumables, accessories, other medical 3D Footplates							0									0				
	Incorrect patient identification							0									0				
Risk18	Slips, lapses and mistakes	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this 3D Footplate	Not performing the clinical stress test properly	Harm to the patient		3	3	9		Information for safety	Only medical professional trained in executing manual clinical stress tests are allowed to use the 3D Footplate	Include in user manual clear warning and intended use	Check update user manual	N	1	3	3	Y	Unauthorized people can still have access to the 3D Footplate	Unauthorized people can use the 3D Footplate	Since the 3D Footplate will be used in medical settings, use by other than medical professionals will likely not happen.
	Functionality																				
	Loss of electrical or mechanical integrity							0									0				
	Deterioration in performance (e.g. gradual occlusion of fluid or gas path, change in resistance to flow, electrical conductivity) as result of ageing, wear and repeated use							0									0				
Risk19	Failure of a component due to ageing, wear or fatigue	Wear or fatigue of components	Parts can break or bend causing product to fail its intended use	3D Footplate cannot perform its intended use		4	2	8		Information for safety	Scheduled maintenance is advised	Include in maintenance manual advice for regular scheduled maintenance; Include in user manual warning regarding lifetime of 3D Footplate		N	4	2	8	Y	Regular monitoring the state of the 3D Footplate, unpredicted failure of the 3D Footplate is prevented	Product fails before use on patients	Include warning in assembly manual that only qualified and trained professionals should manufacture the 3D Footplate; and that a thorough incoming goods inspection should take place for ordered off-the-shelf components
	Security																				
	Unsecured data ports that are							0									0				
	Data without encryption							0									0				
	Software vulnerabilities that can be							0									0				
	Software updates without							0									0				
	SaMD, Algorithms, Artificial																				
	Data collection							0									0				
	Data preparation processing							0									0				
	annotation							0									0				
	labelling							0									0				
	cleaning							0									0				
	enrichment							0									0				
	aggregation							0									0				
	assumptions							0									0				
	data measurement							0									0				
	data representation							0									0				
	Availability, quantity and suitability							0									0				
	Possible biases							0									0				
	Possible data gaps or shortcomings							0									0				
	Data sets							0									0				
	representative							0									0				
	free of errors							0									0				
	complete							0									0				
	training							0									0				
	validation							0									0				
	testing							0									0				