Document control

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Document number	*3.00.3D Fo*	Document date	Document version	1

Document owner(s)	Department, title	Date	Version
E.P. Masih	*Biomechanical engineering, BSc*	*22-3-2024*	*Version 1*
G.J.M. Tuijthof	*Biomechanical engineering, Prof.*	*22-3-2024*	*Version 1*

Document release	Department, title	Date	Version
G.J.M. Tuijthof	*Biomechanical engineering, Prof.*	*11-7-2025*	*Version 1*

Document changes	Department, title	Date	Version	Summary of changes
E. Masih	*Biomechanical engineering, BSc*	*22-3-2024*	*Version 1*	*Filled out Design requirements hardware*
G.J.M. Tuijthof	*Biomechanical engineering, Prof.*	*11-7-2025*	*Version 1*	*Changed template, made all relevant worksheets complete*
G.J.M. Tuijthof	*Biomechanical engineering, Prof.*	*12-9-2025*	*Version 1*	*Final check design requirements*

References

ISO 13485:2016 7.3

University of Twente

TechMed MDR Taskforce & Sustainable Healthcare Technology programme updated by G Tuijthof

Template name	Design and Development
Template number	3.01.01.x
Template version	1.4
Template date	240830

Template change history

210928	Added Design input - Software, renamed Design input to Design input - Hardware
211222	Added reports column to design input
220412	Change description of comparator technologies in design plan, initial clinical evaluation
240830	Added worksheet 'Template instructions', updated layout of worksheets, combined worksheets Design Plan & Review into one sheet

Design & Development Teams

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Team A			
University of Twente			
E.P. Masih	*BSc*	*Student Master Biom*	*23-1-2024*
G.J.M. Tuijthof	*Prof. Dr. Ir.*	*Project lead, ME*	*23-1-2024*
Q. Meinders	*Ing.*	*Technician, IDE*	*23-1-2024*
C.J.W. Haarman	*Dr. Ir.*	*Assistant Lead, BME*	*23-1-2024*

Team B			
Maastricht University Medical Centre			
M. Poeze	*Prof. Dr.*	*Trauma surgeon*	*23-8-2024*
J. Norg	*BSc*	*Student Master Medi*	*23-8-2024*

Design Plan & Review

Italic texts are suggested topics/items to include

Goals & Objectives	Responsible	Tasks	Deliverables	Design Output	Deadline	Reviewer(s)	Independent(s)	Attendees/Team	Date(s)	Items/Documents reviewed	Outcome	Describe FIX/NOGO conditions	Relation Design Change
											[GO/FIX/NO GO]		
Stakeholder analysis	Team A		Requirements	Worksheet 'Design Input Hardware'		GJM Tuijthof					GO		
Patients / public / caretakers	X	Identify user requirements and specifics regarding use environment, analyse easy accessible low-cost production methodologies, confirm no business case											
Medical professionals	X												
Cure / care facilities													
Insurance companies													
Society													
Government													
Production / manufacturing / clean room	X												
Logistics (shipping)													
Disposal / waste													
Environment													
Future developments (product, market, demographics, etc.)													
Purchasing (availability of parts, equipment, materials)	X												
Sterilisation / packaging													
Test facilities (internal & accredited external)													
Valorisation (freedom to operate / Invention Disclosure Form)													
Design requirements	Team A		Requirements	Worksheet 'Design Input Hardware'		GJM Tuijthof			2012,2025		GO		
User requirements	X									https://purl.utwente.nl/essays/96365 Masih_MScThesis_Utwente			
Functional requirements	X												
Performance requirements													
Interface requirements													
Data definition and database requirements													
Installation and acceptance requirements													
Security requirements													
Conceptual Design	Team A					GJM Tuijthof			2006,2012		GO		
Defining technical principle	X	Has been done in the past, Calculate strength and stiffness of critical parts using SolidWorks		Mimicking manual clinical stress test, Load based positioning in space, Stewart platform						http://doi.org/10.1016/j.ergon.2011.10.006 H. v.d. Zwaag, MSc thesis Design of a device for performing stress CT in in-vivo analyses of hindfoot kinematics, TU Delft 2006			
Brainstorming	X												
Quick calculations various options													
Concept categorization													
Concept selection	X												
Embodiment Design	Team A					GJM Tuijthof			2012, 2023, 2025		GO		
Elaboration in mechanical CAD design	X			CAD design, Bill of materials, lasercut drawing, STL files for 3D printing						Masih_MScThesis_Utwente			
Elaboration in electronic design													
Elaboration in software architecture													
Finite element simulations													
Simulations performance electronic circuits													
Technical evaluation	Team A					GJM Tuijthof		Team B	2025		GO		
Software testing				Prototype, Assembly evaluation, Mechanical performance, User evaluation						https://purl.utwente.nl/essays/96365 Masih_MScThesis_Utwente			
Prototyping	X												
Technical tests mechanical	X												
Technical tests electronic													
Technical tests software													
Technical tests complete design													
Technical test user interface	X												
Initial clinical evaluation	Team A					GJM Tuijthof		Team B	2012, 2025		GO		
Scientific, medical and other literature	X			Risk analysis file, Scientific journal publications, Thesis reports						http://doi.org/10.1016/j.ergon.2011.10.006 doi: 10.1177/0363546512455403; doi: 10.1016/j.arthro.2011.11.030			
Clinical experience data	X												
Clinical investigation													
Regulatory data (classification / recall)													
Risk-benefit evaluation	X												
Pre-clinical studies	X									M. Pontesselli, Bsc thesis Evaluation of a device for performing stress CT in in-vivo analyses of hindfoot kinematics, AUMC, 2008			
Any relavant comparator, any other device or medication													
Pre-clinical evaluation	Team A					GJM Tuijthof		Team B	2012, 2025		GO		
Scientific pre-clinical literature search		Input to risk analysis clinical perspective								https://purl.utwente.nl/essays/96365			
Risk assessment	X									Masih_MScThesis_Utwente http://doi.org/10.1016/j.ergon.2011.10.006			
In-design calculations													
Bench tests	X												
Laboratory tests													
In vitro tests													
Ex vivo tests													
Animal tests													
Mechanical and/or electrical (& EMC) tests													
Reliability tests													

Design Input Hardware

ID#	Requirements from article of Tuijthof (2012)	Quantitative limits	Applicable standards	Associated risk ID's (if appli	Verification required?	Validation required	Ver/Val reports
					Did we build the product r	*Did we build the right product?*	
Req1	The device should be able to manually position the foot in extreme positions relative to the lower leg mimicking a clinical stress test	DF 45 degrees, PF 85 degrees, In 55 degrees, EV 55 degrees, IR 50 degrees and ER 50 degrees.	ISO 11228-2		Yes		3D Footplate preclinical validation; http://doi.org/10.1016/j.ergon.2011.10.006
Req2	It should be clear (unambiguous) how to position the lower leg and the foot in the device	Median error of 0 in positioning of foot and lower leg	IEC62366	Risk13, Risk14	No	Yes	http://doi.org/10.1016/j.ergon.2011.10.006
Req3	The device should be dimensioned such that it can be used to diagnose 95% of an adult human population.	Data from DINED database	CEN-ISO/TR 7250-2		Yes	No	http://doi.org/10.1016/j.ergon.2011.10.006
Req4	The device should be dimensioned such that it fitted into CT scanner bore				Yes	Yes	3D Footplate preclinical validation; doi: 10.1177/0363546512455403; doi: 10.1016/j.arthro.2011.11.030
Req5	The device should be fabricated with materials that can be used in the CT scanner	Metal parts within the device should not cause artefacts that compromise CT-imaging in terms of diagnosis, preoperative planning and processing to 3D kinematics of bones	UIT 78:2018 nl	Risk7	Yes	Yes	6.3D Footplate preclinical validation; Norg_MScThesis_TU Eindhoven; doi: 10.1177/0363546512455403; doi: 10.1016/j.arthro.2011.11.030
Req6	The weight of the device should be a maximum to be portable	< 12.7 kg	ISO 11228-1		Yes	No	6.3D Footplate preclinical validation
Req7	The device should require a separate manual fixation mechanism to preserve the desired extreme position of the foot		ISO 9241-11, ISO 10075-2	Risk2, Risk7, Risk8, Risk14	Yes	Yes	6.3D Footplate preclinical validation
Req8	Different hand grips on the device should be allowed to apply manual loading.		ISO 111228-2, ISO 9241-11	Risk16, Risk17, Risk18	Yes	No	6.3D Footplate preclinical validation
Req9	The total imaging acquisition time should not be increased by more than a maximum of 10-15 % when using the device				No	Yes	6.3D Footplate preclinical validation; http://doi.org/10.1016/j.ergon.2011.10.006
Req10	The device should be operated by one person	median error of 0 and maximum operation time of 250 s	IEC62366		No	Yes	6.3D Footplate preclinical validation
Req11	The device should offer fast operation	< 100 s	IEC62366		No	Yes	6.3D Footplate preclinical validation; http://doi.org/10.1016/j.ergon.2011.10.006
Req12	The device should be able to manually fixate the foot in extreme positions relative to the lower leg	DF 45 degrees, PF 85 degrees, In 55 degrees, EV 55 degrees, IR 50 degrees and ER 50 degrees.	ISO 11228-2; IEC62366		Yes	No	6.3D Footplate preclinical validation
Req13	The user should have a sense of control when using the device	> 7 on likert scale of 0-10 with 10 being full control	IEC62366		No	Yes	NO EVIDENCE YET of this version of 3D Footplate
Req14	Excursions of the upper extremities of the user should be kept within limits	RULA score ≤ 3	ISO 11226, ISO 11228-3 RULA - Rapid Upper Limb Assessment		No	Yes	NO EVIDENCE YET
Req15	Fixating the foot should not create additional damage to the ligaments			Risk15, Risk16, Risk17, Risk18	No	Yes	NO EVIDENCE YET, only 2.02.3D Footplate User manual v3.0
Req16	The device should have a professional appearance and blend into the working environment	> 7 on likert scale of 0-10 with 10 being full professional appearance	IEC62366		No	Yes	NO EVIDENCE YET of this version of 3D Footplate; http://doi.org/10.1016/j.ergon.2011.10.006
Req17	The device should be operated with minor physical and mental effort	< 15%	NASA Task Load Index (NASA TLX)		No	Yes	NO EVIDENCE YET of this version of 3D Footplate; http://doi.org/10.1016/j.ergon.2011.10.006
ID#	**Requirements from thesis of van Elst (2023) and Masih (20**	**Quantitative limits**	**Applicable standards**	**Associated risk ID's (if applicable)**	**Verification required?**	**Validation required**	**Ver/Val reports**
							Masih_MScThesis_Utwente; https://purl.utwente.nl/essays/96365
Req18	The materials that come into contact with the patient must be biocompatible		ISO 10993	Risk6	Yes	No	3.03.3D Footplate Bill of Materials v1.2
Req19	The device should not exceed 5 mm of deflection when the foot is fixated.	Bending deflection ≤ 5 mm		Risk3, Risk10, Risk19	Yes	No	6.3D Footplate preclinical validation

Req20	The straps on the device where the foot is attached should be released in one movement	timing release within 5 sec. and in 1 motion		Risk4	Yes	Yes	6.3D Footplate preclinical validation
Req21	The device must be easy to clean	ATP level < 250 ppm. Time and effort of cleaning	ISO 17664	Risk5, Risk12	Yes	No	2.02.3D Footplate User manual v3.0
Req22	The device should at least be functional without maintenance	> year without maintenance		Risk8	No	Yes	NO EVIDENCE YET, only 2.02.3D Footplate Maintenance manual v1.0
Req23	The device should not break when accidently falling during transport			Risk1	No	Yes	NO EVIDENCE YET, only 2.02.3D Footplate User manual v3.0
Req24	The device should only be used by someone with a medical background who has also received training in clinical stress tests			Risk15, Risk17, Risk18	No	Yes	2.02.3D Footplate User manual v3.0
Req25	The device have no sharp edges				Yes	No	6.3D Footplate preclinical validation

Design Change

Note that column D, L-P contain dropdown menus to be filled out

Change #	Date	Part/Process	Phase	Description of change	Why was this change implemented?	Who approved it?	Date of implementation	Who implemented?	Comments	Objective evidence of effectiveness	Update Risk Analysis?	Update Intended Use?	Update GSPR?	Update labels/IFU?	Ver / Val required?
1	23-1-2024	Ground plate assembly	INPUT	The ground plate assembly is completely changed allowing for assembly without the use of glue. Locks are added to ensure that the assembly stays in place.	Glue deteriorates over time and PP glue is expensive	G.J.M. Tuijthof	23-1-2024	C.J.M Haarman			N/A	NO	N/A	NO	N/A
2	26-3-2024	Connection between plate and rods	INPUT	Selected an off-the-shelf cardan	The rubber connection was not suitable to reach the angular range. Finding an alternative was therefore necessary	G.J.M. Tuijthof	26-3-2024	Q. Meinders			N/A	NO	N/A	NO	NO
3	24-4-2024	Rods	INPUT	Selected off-the-shelf PVC tubes as rods	For a telescopic clamp assembly rods that fit into each other are necessary	G.J.M. Tuijthof	24-4-2024	E.P. Masih	Unsure if the material is not too prone to bending		N/A	NO	N/A	NO	NO
4	24-4-2024	Telescopic clamp	INPUT	Selected off-the-shelf telescopic clamp	The telescopic clamp will allow for a telescopic rods system that is easily to use by the user of the device.	G.J.M. Tuijthof	24-4-2024	E.P. Masih	The price of shipment for the clamp needs to be checked		N/A	NO	N/A	YES	NO
5	1-5-2024	Telescopic clamp	CHANGE	Telescopic clamp will be a 3D printed component	The off-the-shelf telescopic clamp was too expensive in terms of shipment costs, since it had to be ordered from the US.	Q. Meinders G.J.M. Tuijthof	1-5-2024	E.P. Masih	The clamping function of the telescopic rods system needs to be tested with 50N force pulling or pushing on the end of the rods		N/A	NO	N/A	YES	YES
6	1-5-2024	Ball-in-socket joint	INPUT	Selected off-the-shelf plastic ball-in-socket joint	The 3D printed ball-in-socket joints from the design of D. van Elst required a pre-processing step involving countersinking. This was deemed too difficult for what should be an easy assembly. These new ball-in-socket joints have a threaded end, which can easily be tightened to the back plate with a screw or hex bolt.	G.J.M. Tuijthof	1-5-2024	E.P. Masih			N/A	NO	N/A	NO	NO
7	3-5-2024	Telescopic clamp	INPUT	Selected bolt with cross nut to allow the lever to be turned	Turning the lever will allow the clamp to be opened and closed	G.J.M. Tuijthof	3-5-2024	E.P. Masih	These were only available in metal, which means metal is introduced in the device		YES	NO	N/A	NO	NO
8	3-5-3024	Telescopic clamp	INPUT	Selected a screw to go in the lever and bolt with cross nut	A screw connects the lever to the clamp and can be used to adjust the degree of clamping	G.J.M. Tuijthof	3-5-2024	E.P. Masih	More metal is introduced		YES	NO	N/A	NO	NO
9	7-5-2024	Rods	CHANGE	Selected PMMA tubes as rods Ø22-18mm and Ø18-14mm	The PVC tubes where not strong enough to withstand bending	G.J.M. Tuijthof	7-5-2024	E.P. Masih			N/A	NO	N/A	NO	NO
10	7-5-2024	Connector foot plate to cardan	INPUT	Selected off-the-shelf expanding screw	A screw is easy to mount to the plate and it is a solution without the use of metal	G.J.M. Tuijthof	7-5-2024	E.P. Masih			N/A	NO	N/A	NO	NO
11	7-5-2024	Connector thick rod to ball-in-socket joint	INPUT	Selected off-the-shelf insertion cap with threaded inside	The thread of the ball-in-socket joint can be screwed in the insertion cap. The insertion cap can be hammered into the thick rod	G.J.M. Tuijthof	7-5-2024	E.P. Masih			NO	NO	N/A	NO	NO

12	8-5-2024	Rods	CHANGE	Changed the diameters of the PMMA tubes to Ø25-21mm and Ø20-16mm	Due to a check on the tolerances of PMMA tubes, it has been determined that 18mm in 18mm has a chance of fitting too tightly	Q. Meinders	8-5-2024	E.P. Masih			N/A	NO	N/A	NO	NO
13	8-5-2024	Connection between cardan and rods	INPUT	Decided to use a clamp to connect these 2 cilindrical components	A second clamp makes for a logical assembly process	G.J.M. Tuijthof	8-5-2024	E.P. Masih			N/A	NO	N/A	NO	NO
14	11-6-2024	Ground plate assembly	CHANGE	Locks have been changed to have a clip on it	When the locks are pressed in the holes, the clip is pressed in too. When the locks are through the hole, the clip expands again. This allows for a reliable fitting accounting for a large tolerance	Q. Meinders	11-6-2024	E.P. Masih			N/A	NO	N/A	NO	NO
15	13-6-2024	Connector foot plate to cardan	CHANGE	Selected a brass insert to insert in the cardan, allowing for a threaded inside that can be used to with a screw to connect the plate to the cardan	The expanding screw did not expand enough and ended up not clamping enough to connect the plate and the cardan	G.J.M. Tuijthof	13-6-2024	E.P. Masih	The insert is from brass, which means more metal is introduced in the device.		YES	NO	N/A	NO	NO
16	17-7-2024	Heel support	INPUT	Implemented a similar lock system for the heel support platform	The previous design of D. van Elst required glue to attach the heel support to the foot plate	Q. Meinders	17-7-2024	E.P. Masih			N/A	NO	N/A	NO	NO
17	7-8-2024	Heel support	CHANGE	Less tapered heel support	One heel support locks kept falling out of the hole	G.J.M. Tuijthof	7-8-2024	E.P. Masih			N/A	NO	N/A	NO	NO
18	7-8-2024	PMMA rods	CHANGE	The length of the rods need to be shortened from 220mm each to 200mm for the thin rod and 175mm for the thick rod	To fulfill requirement #2	G.J.M. Tuijthof	7-8-2024	E.P. Masih			N/A	NO	N/A	NO	NO
19	21-8-2024	Velcro straps	INPUT	Velcro straps are added to the device	The previous design of D. van Elst required glue and sewing. This is changed to be easier to assemble	G.J.M. Tuijthof	21-8-2024	E.P. Masih			NO	NO	N/A	NO	NO
20	23-8-2024	Velcro straps	CHANGE	The Velcro straps are made longer	From the usability test it was concluded that the clinician could not easily attach a person's foot to the device, because the straps where too small to properly hold while pulling	G.J.M. Tuijthof	23-8-2024	E.P. Masih			N/A	NO	N/A	NO	N/A
21	23-8-2024	Ground plate assembly; side plate	CHANGE	A part of the railing is removed	The bottom clamps are not easily reached. By laser cutting a part of the rails, it will be easier to reach those	G.J.M. Tuijthof	23-8-2024	E.P. Masih			N/A	NO	N/A	NO	N/A
22	23-8-2024	Ground plate assembly	INPUT	Added anti-slip tape to the bottom of the ground plate assembly	The device might be able to slip on the CT scanner table. To prevent this, anti-slip tape is added	G.J.M. Tuijthof	23-8-2024	E.P. Masih			N/A	NO	N/A	NO	N/A