DOCUMENT TYPE	DOCUMENT OWNER	PRODUCT NAME
Preclinical tests	**GJM Tuijthof**	**3D Footplate**
TITLE	RELEASED BY	DATE
6.3D Footplate preclinical validation	**GJM Tuijthof**	**24-08-2025**

Document change history

BY	DATE	VERSION	SUMMARY OF CHANGES
E. Masih	01-09-2024	01	Text spelling check, update images
GJM Tuijthof	24-08-2025	01	Added front page, optimized layout
GJM Tuijthof	12-09-2025	01	changed telescopic clamp, added introduction, cadaver test, reference to risk IDs

3D Footplate preclinical validation

Introduction

This document provide a summary of tests and their results performed in previous studies:

- http://doi.org/10.1016/j.ergon.2011.10.006
- vanElst_MScThesis_UTwente
- Masih_MScThesis_UTwente
- Norg_MScThesis_TU Eindhoven
- Additional verification tests.

Each test is described with a table containing the following items

1. Test ID indicates a Unique identification number and name to be traced back.

2. REQUIREMENT(S) refer to the requirements ID in line with 300.3D Footplate DesDev v1.4, worksheet 'Design Input Hardware'

3. CONDITION shows the test condition, whether it is a visual check, a verification test or a validation test

4. INPUT shows a description of the input. This can be done in the form of an instruction in case visual checks are needed.

5. OUTPUT describes the expected/required output.

6. CONCLUSION describes PASS/FAIL. If result of test is equal to the expected output, then the result is pass. Otherwise this is fail.

Test ID	Test 1 (3D Footplate main parameters verification)
REQUIREMENT(S)	Req1, Req3, Req4, Req6, req8, Req12, Req25
CONDITION	Verification of range of motion, dimensions and weights
INPUT	**1. Check if 3D Footplate can reach 45 degrees in dorsiflexion (DF)** By goniometer and visual check of 3D Footplate **2. Check if 3D Footplate can reach 85 degrees in plantar flexion (PF)** By goniometer and visual check of 3D Footplate **3. Check if 3D Footplate can reach 55 degrees in inversion (IN)** By goniometer and visual check of 3D Footplate **4. Check if 3D Footplate can reach 55 degrees in eversion (EV)** By goniometer and visual check of 3D Footplate **5. Check if 3D Footplate can reach 50 degrees in internal rotation (PF)** By goniometer and visual check of 3D Footplate **6. Check if 3D Footplate can reach 50 degrees in external rotation (ER)** By goniometer and visual check of 3D Footplate **7. Check if 3.02.3D Footplate_Footplate has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit **8. Check if 3.02.3D Footplate_Heel Support has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit **9. Check if 3.02.3D Footplate_Heel lock has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit **10. Check if 3.02.3D Footplate_cross_large has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit **11. Check if 3.02.3D Footplate_back has dimensions and angle as shown in CAD model** By vernier caliper, and visual check of component fit **12. Check if 3D Footplate_Tube_large has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit

	13. Check if 3D Footplate_Tube_small has dimensions as shown in CAD model By vernier caliper, and visual check of component fit **14. Check if 3.02.3D Footplate_Side has dimensions as shown in CAD model** By vernier caliper, and visual check of component fit **15. Check if 3D Footplate fits within the CT scanner bore** By visual check of component fit **16. Check if 3D Footplate weighs less than 12.7 kg** By pair of weighing scales **17. Check if 3D Footplate component Footplate can be hold with different hand grips** By visual inspection of different hand grips **18. Check if 3D Footplate has no sharp edges** By visual inspection of different hand grips
OUTPUT	The test is passed when all **bold** lines are passed
CONCLUSION	PASS

Test ID	**Test 2 (3D Footplate usability check)**
REQUIREMENT(S)	Req2, Req9, Req10, Req11, Req13, Req14, Req17
CONDITION	Validation update of previous usability study Note: http://doi.org/10.1016/j.ergon.2011.10.006, presents a complete usability study of a previous version of the 3D Footplate. We reasons that because that almost all aspects regarding the functionality and use of the 3D Footplate have been kept the same in the current open source version of the 3D Footplate, the results of that study are still valid. The main difference between the pervious design and the current 3D Footplate is that the fixation of the rods is performed with telescopic clamps instead of a single handle. We feel that as this type of clamp is a generally known mechanism for example used in bicycle saddles to adjust their height, no issue will arise regarding Risk14, and we verified this with a single user.
INPUT	**1. Goal:** The aim of the usability test is to validate the usability of the device, because the fixation system has been changed.

<table>
<tr><td></td><td>
Methods: The usability is tested through a demonstration by one clinician. The clinician was asked to position the foot in the neutral position, plantar flexion and a position of his choice. After that a short questionnaire was filled out:
On a scale of 1-5, to what extent can you perform the stress test as intended?
On a scale of 1-5, to what extent is it easy to operate the device by yourself?
On a scale of 1-5, how much effort does it take to operate the device? Both mentally and physically.

2. Verification of use time of 3D Footplate starting with guiding the patients lower leg into the 3D Footplate until fixated in an extreme position
By recording the time multiples times
</td></tr>
<tr><td>OUTPUT</td><td>
1. Results
<table>
<tr><td>Question</td><td>Answer</td></tr>
<tr><td>On a scale of 1-5, to what extent can you perform the stress test as intended?</td><td>4, the Velcro is too short to be properly operated.</td></tr>
<tr><td>On a scale of 1-5, to what extent is it easy to operate the device by yourself?</td><td>5, the clamps make it easy to operate the device with one person.</td></tr>
<tr><td>On a scale of 1-5, how much effort does it take to operate the device? Both mentally and physically.</td><td>Mentally 1.
Physically 0.</td></tr>
</table>
Two additional remarks were made. 1) The clinician found the third Velcro strap for foot fixation not useful, because it did not assist in the attachment of the foot. 2) The lower clamps are difficult to reach when the 3D Foot Plate is placed into a position close to the bottom of the device.

</td></tr>
</table>

	Figure 1: Usability test with a clinician. A: The foot fixated in plantar flexion position. B: The foot fixated in a position of the clinician's choice. The Velcro straps need to be longer, which was immediately remedied by cutting new straps. It is difficult to reach the lower clamps. This has been compensated for by advising the user in the IFU to heighten the patient's foot in the device through an extra towel underneath the calf. **2. Result: average fixation time is 60 seconds**
CONCLUSION	PASS

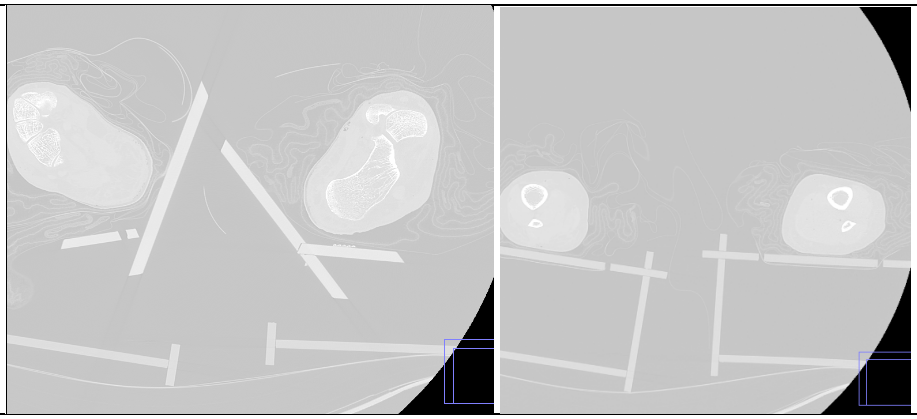
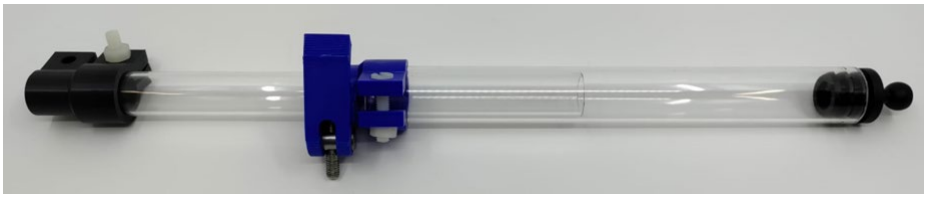
Test ID	**Test 3 (3D Footplate imaging check)**
REQUIREMENT(S)	Req5, Req7
CONDITION	Validation
INPUT	Cadaver test with 2 human lower legs. 5 CT scans were made of the cadavers, using the 3D Footplate by fixating the cadaver feet relative to the lower leg in various conditions: feet in neutral position, extreme dorsiflexion, extreme plantarflexion, extreme eversion, and extreme inversion. **1. Check if fixation is in various positions is achieved and maintained** By visual inspection and that of CT-scans (Figure 2) **2. Check if image artefacts do not influence image interpretation** By visual inspection of CT scans (Figure 2) **3. Verify proper segmentation of bones** By performing segmentation and comparing segmented bones to actual CT scans
OUTPUT	

	Figure 2. Left: screenshot CT-image ankle area, Right; screenshot CT-image lower leg area. In both images plastic components can be clearly seen, but give no material artefacts, neither motion artefacts are detected  *Figure 3. Screenshot segmentation of the CT from Figure 1.* Both images demonstrate no material or motion artefacts.
CONCLUSION	PASS

Test ID	**Test 4 (3D Footplate fixation check)**
REQUIREMENT(S)	Req7
CONDITION	Verification friction force
INPUT	**Goal:** The aim of the friction test is to ensure that the new clamping mechanism consisting the telescopic clamp and the PMMA rods generates enough friction for the Stewart platform to stay in place when applying the maximum tensile force of at least 50N. **Methods:** The clamp-rod assemblies (Figure 4) are pulled by an unster (Figure 5) with a resistance of at least 60 N, while the lever of the telescopic clamp is in a closed state. This is held for 2 minutes and repeated 10 times. All telescopic clamp-rod assemblies were tested.  *Figure 4: Picture of one clamp-tube assembly. In blue the telescopic clamp.*

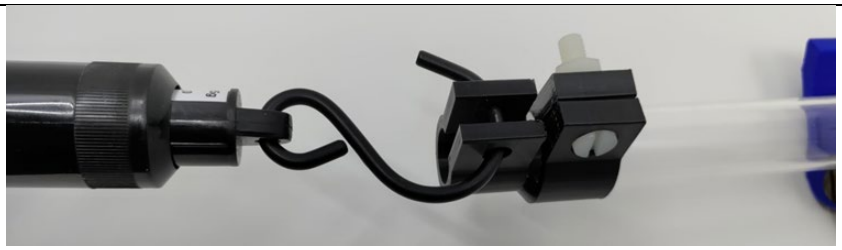


Figure 5: The hook of the unster is pulled through the screw holes of the permanent clamp. Force is applied by pulling the unster while the telescopic clamp is in closed-state.

OUTPUT

The results are shown in Table 1. All attempts per clamp-rod assembly were successful.

Table 1: Overview containing the successfulness of the test per assembly and per test. "Yes" means that the test was successful and "No" means that the test was unsuccessful.

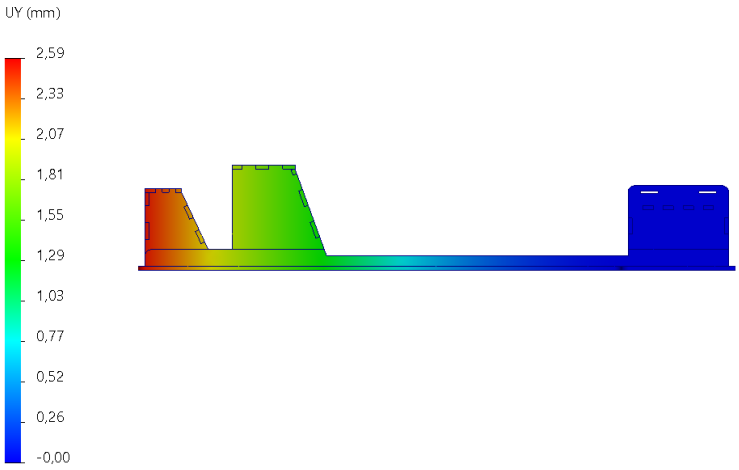
Assembly # /Attempt #	1	2	3	4	5	6	7	8	9	10
1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

All telescopic clamps can withstand 60N.

CONCLUSION

PASS

Test ID	**Test 5 (3D Footplate stiffness check)**
REQUIREMENT(S)	Req19
CONDITION	Verification using finite element analysis
INPUT	A simulated deformation test has been carried out using SolidWorks (Version 2022) to see what the maximum bending of the ground plate is when it is loaded by pulling the ropes. In this case, an unrealistic pressure of 100 $Nm2/$ has been applied to the top of the back side. This pressure is applied in the upward direction. As you can see in Figure 6. This is not the current design of

	the 3D Footplate. However, the same material was used and this design was even less resistant to bending. So, this can be considered as a worst case scenario.
OUTPUT	The maximum deflection, directed upwards (y direction), is 2.59 mm.  *Figure 6: Deformation profile.*
CONCLUSION	PASS

Test ID	**Test 6 (3D Footplate release)**
REQUIREMENT(S)	Req20
CONDITION	Validation
INPUT	**Goal:** The aim of the test is to validate/verify that the foot of the patient can be released from the device within a timespan of 7 seconds. **Methods**: Two individuals were asked to participate in this test (Figure 7) by releasing a foot from the device three times. They were instructed to start releasing when the person in the device said “ow”. Their times were recorded with a smartphone timer.

	 *Figure 7: Release test, showing the foot in the 3D Foot Plate, an individual ready to release the foot and the smartphone timer used to record the time.*
OUTPUT	Person 1: 6.09 seconds, 5.46 seconds, 4.92 seconds. Mean: 5.49 seconds Person 2: 5.21 seconds, 5.04 seconds, 4.86 seconds. Mean: 5.04 seconds The foot was released within a timespan of 7 seconds for each attempt. As the results show, the amount of time decreased with each try.
CONCLUSION	PASS

Test ID	**Test 7 (3D Footplate assembly)**
REQUIREMENT(S)	Req29
CONDITION	Validation
INPUT	**Goal**: The aim of the assembly test was to evaluate the ease of assembly of the 3D Foot Plate. **Methods**: An individual was provided with the materials, assembly manual and equipment for assembling the 3D Foot Plate. The equipment included: a set of screwdrivers, scissors, a nylon hammer and a bench vise. A recording was made to keep track of the assembly time and number of mistakes.
OUTPUT	The assembly took 50 minutes. Two mistakes were made: (1) an M5 bolt and nut were used for both sides of the small clamps, instead of an M5 for one side and an M6 for the other side and (2) the alignment of the cardan with the small clamp was incorrect.

Figure 8: Screenshot of the recorded assembly test. Shown are the assembly manual on the laptop, the materials and the equipment.

Figure 9: The picture displays the result of two errors made during the assembly test. In the white circle, the misalignment error can be viewed. The distance discrepancy is shown in red. The second error is indicated by the blue circle.

	The mistakes made during the assembly test were minor, but could be easily prevented by small changes in the assembly manual, which have been done. A warning that is given for the alignment step.
CONCLUSION	PASS