Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION WITH HUMAN SUBJECT RESEARCH

This report should be completed for every experimental device that is to be used in interaction with humans and that is not CE certified or used in a setting where the CE certification no longer applies[1].

The first part of the report has to be completed by the researcher and/or a responsible technician.

Then, the safety officer (Heath, Security and Environment advisor) of the faculty responsible for the device has to inspect the device and fill in the second part of this form. An actual list of safety-officers is provided on this webpage.

Note that in addition to this, all experiments that involve human subjects have to be approved by the Human Research Ethics Committee of TU Delft. Information on ethics topics, including the application process, is provided on the HREC website.

Device identification (name, location): Wrist immobilizer, Delft (transportable)

Configurations inspected[2]: Disassembled before application to the participant and assembled around the arm.

Type of experiment to be carried out on the device:[3] Test of fitting and comfort and test of ease of application

Name(s) of applicants(s): Karin Thomassen

Job title(s) of applicants(s): PhD student

(Please note that the inspection report should be filled in by a TU Delft employee. In case of a BSc/MSc thesis project, the responsible supervisor has to fill in and sign the inspection report.)

Date: 17-7-2023

Signature(s): 

1 Modified, altered, used for a purpose not reasonably foreseen in the CE certification

2 If the devices can be used in multiple configurations, otherwise insert NA

3 e.g. driving, flying, VR navigation, physical exercise, ...

Setup summary

Please provide a brief description of the experimental device (functions and components) and the setup in which context it supposed to be used. Please document with pictures where necessary.

More elaborate descriptions should be added as an appendix (see below).

The function of the device is to immobilize the wrist joint. This is done with an adaptable frame with separately adaptable pads that support the arm and hand.

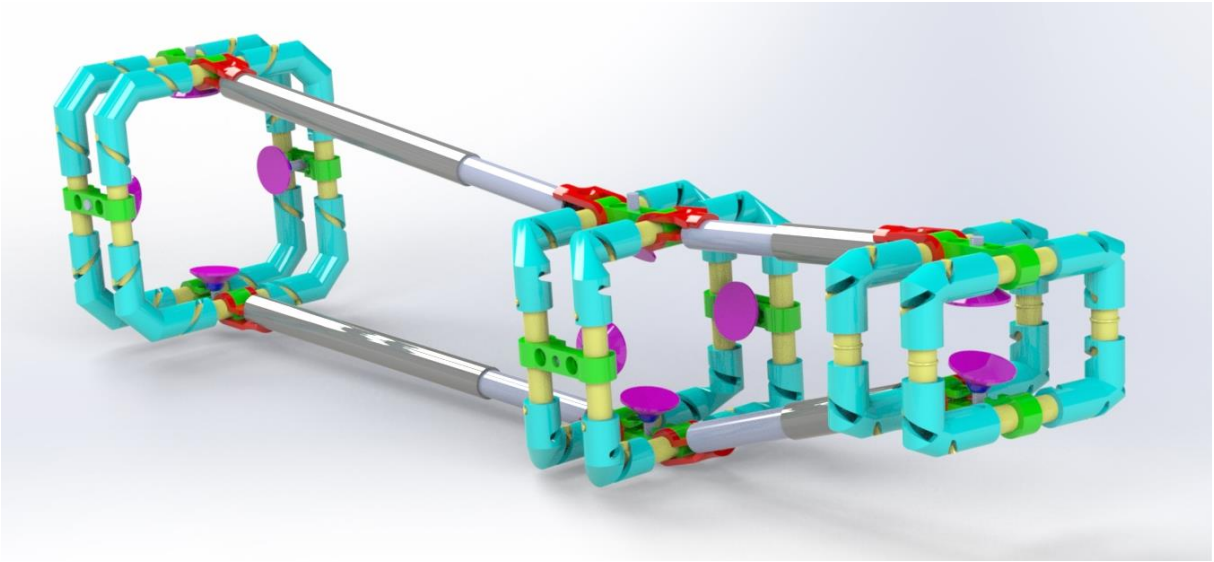
The experiment will take place in a room with a healthy participant and the researcher. The participant will be informed about the experiment. The researcher will apply the device to the arm and wrist of the healthy volunteer, the volunteer will wear the device for about 10 minutes while doing some simple tasks. Furthermore some measures are taken of the arm of the volunteer (without device).

For the application the yellow parts will be turned to adapt the ring size. The grey parts will be fixated in the right length. The green and red parts will be fixed with a bolt and the bolt of the dark blue-pink part will be tightened to a comfortable pressure on the arm.

In the second part of the experiment the volunteer will apply the device to the researcher (or possibly another volunteer) to investigate the ease of application.

For both parts some questions will be answered.

Below the current version of the device:



Risk checklist

Please fill in the following checklist and consider these hazards that are typically present in many research setups. If a hazard is present, please describe how it is dealt with.

Also, mention any other hazards that are present.

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	yes	The device is adaptable and therefore there are moving parts. Sharp edges are not present	It is operated manually and only low forces apply. Communication with the participants about their comfort avoids problems with the moving parts.
Electrical	No		
Structural failure	Yes	The device can break if a too large load is applied	Structural failure will not lead to hazards. Possibly sharp edges can be formed. The experiment will be stopped immediately if the device breaks
Touch Temperature	No		
Electromagnetic radiation	No		
Ionizing radiation	No		
(Near-)optical radiation (lasers, IR-, UV-, bright visible light sources)	No		
Noise exposure	No		
Materials (flammability, offgassing, etc.)	No		
Chemical processes	No		
Fall risk			
Other: Skin	Yes	The pads are located directly on the skin this could cause irritation	Communication with the participant, if irritation occurs the experiment will be stopped. With mild discomfort the test can be continued.
Other:			
Other:			

Appendices

Here, you may add one or more appendices describing more detailed aspects of your setup or the research procedures.

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name: Peter Kohne

Faculty: 3mE- IO

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

Date: 19-07-2023

Signature: 

Inspection valid until[4]:

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

4 Indicate validity of the inspection, with a maximum of 3 years