

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 applies¹.

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

Then, the safety officer (Health, 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): Low-cost Laparoscope, Delft

Configurations inspected²: 1

Type of experiment to be carried out on the device:³

Laparoscopic surgery training exercise

Name(s) of applicants(s):

Roos Oosting

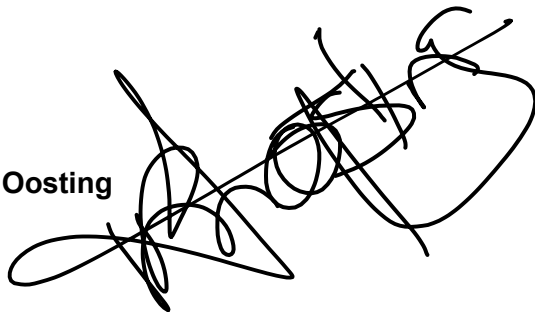
Job title(s) of applicants(s):

Assistant Professor

(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: 02-04-2026

Signature(s): Roos Oosting

A handwritten signature in black ink, appearing to be 'Roos Oosting', written over a horizontal line.

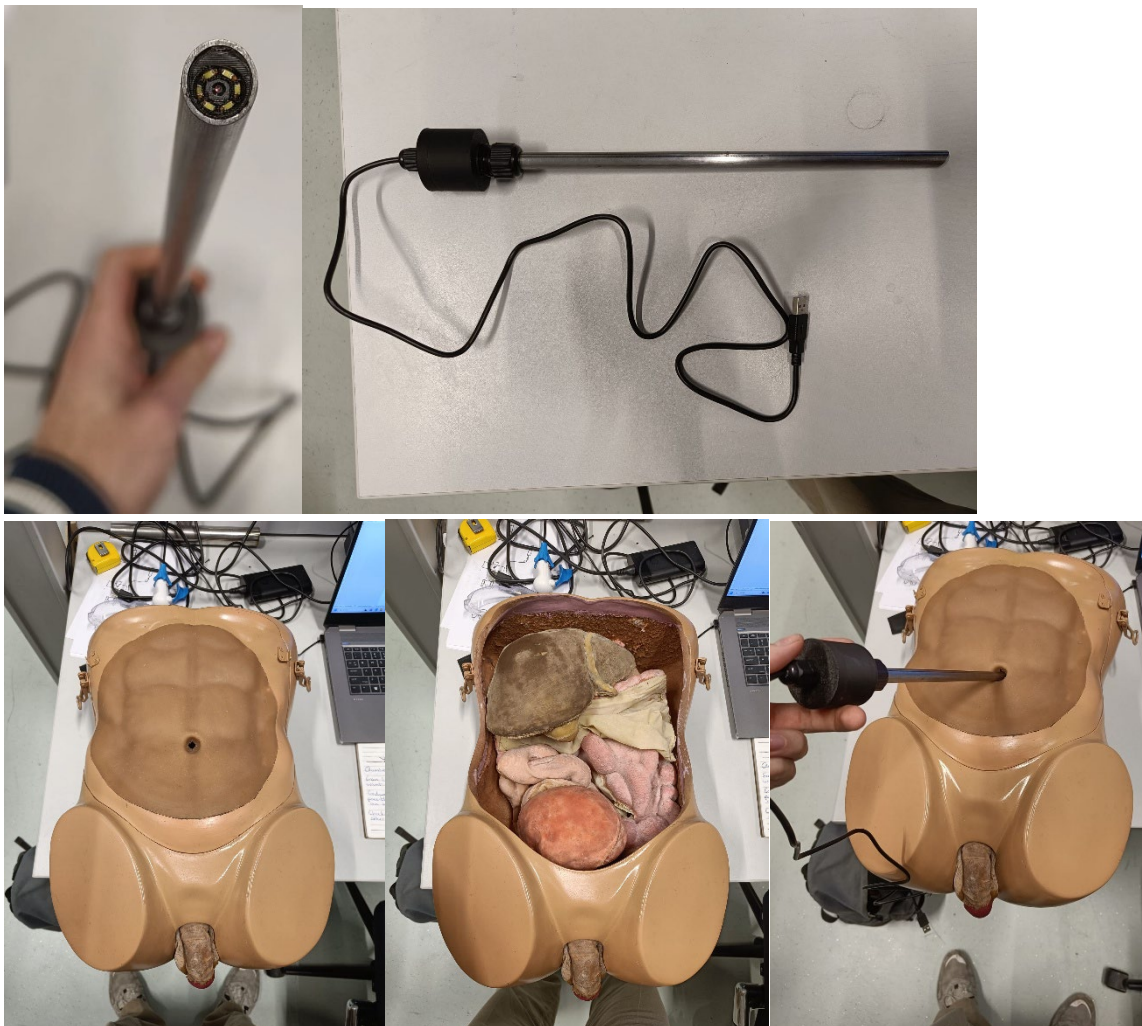
- 1 Modified, altered, used for a purpose not reasonably foreseen in the CE certification
- 2 If the devices can be used in multiple configurations, otherwise insert NA
- 3 e.g. driving, flying, VR navigation, physical exercise, ...

Setup summary

The device is a low-cost laparoscope. This is a surgical instrument that is used to view the inside of the abdomen.

It consists of a USB camera inside a metal shaft with a handle at the end for maneuvering the scope. (see pictures for clarification)

For the experiment, participants will be asked to identify several organs inside a training doll. Afterwards they are asked questions on the image quality and usability of the scope.



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.)	x		Sharp edges have been rounded off
Electrical	x		All electrical parts are enclosed in the device. Participants cannot be electrocuted
Structural failure			
Touch Temperature	x		Device does not get warmer than 30 degrees Celsius
Electromagnetic radiation			
Ionizing radiation			
(Near-)optical radiation (lasers, IR-, UV-, bright visible light sources)			
Noise exposure			
Materials (flammability, offgassing, etc.)			
Chemical processes			
Fall risk			
<i>Other:</i>			
<i>Other:</i>			
<i>Other:</i>			

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: Maarten Lugt

Faculty: Mechanical Engineering

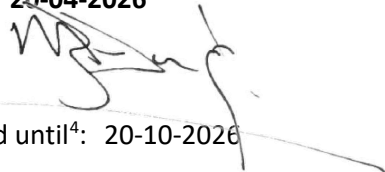
The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

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

There are no additional risks foreseen for the participants, using this device on a training doll.

Date: 20-04-2026

Signature:



Inspection valid until⁴: 20-10-2026

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