

Master thesis

---

# Appendix

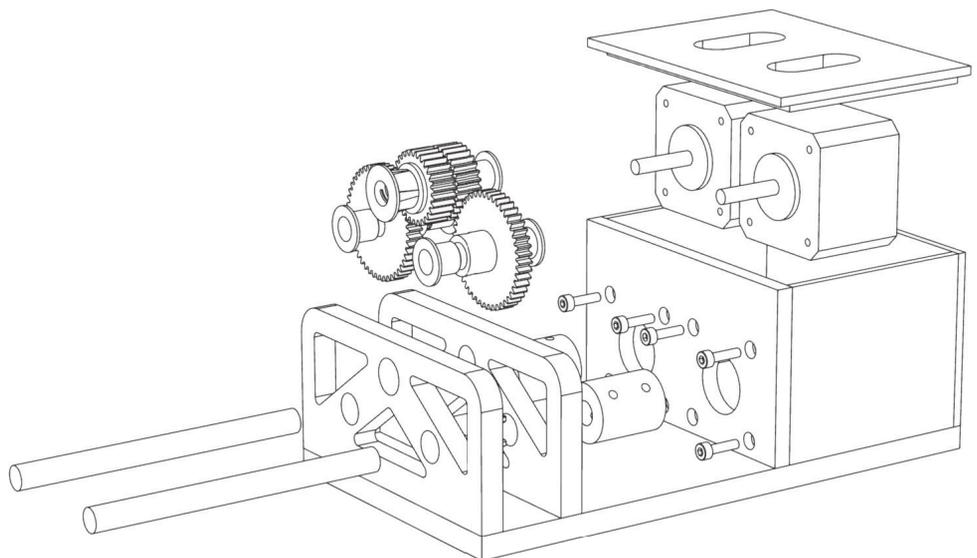
Design of a needle control device for MRI-guided intervention

Graduate student  
Charlotte Kemp

Supervisory team  
R.H.M. Goossens  
A.L.M. Minnoye  
D.G.H. Bosboom

Delft, February 2020

Delft University of Technology  
Faculty Industrial Design Engineering  
Master Integrated Product Design  
Specialisation Medesign



**Appendix**  
**Delft, February 2020**

**Education**

Master Integrated Product Design  
Medisign specialization  
Faculty of Industrial Design Engineering  
Delft University of Technology

**Client**

Radboud Universitair Medisch Centrum  
Department of Radiology and Nuclear Medicine  
Nijmegen

Soteria Medical BV  
Arnhem

**Supervisory team**

*Project chair*

Prof. dr. ir. Goossens, R.H.M.  
Professor of Physical Ergonomics, Head of Industrial Design  
Department

*Project mentor*

Ir. Minnoye, A.L.M.  
Lecturer and tutor in Design Engineering

*Company mentor*

Drs. Bosboom, D.G.H.  
Radiologist at the Radboudumc and CSO at Soteria Medical  
BV

**Author**

A.C. Kemp  
studentnumber 4285212  
contact: charlotte-kemp@hotmail.com



# Appendix

Design of a needle control device for MRI-guided intervention



# Appendices

---

- Appendix I – Project brief
- Appendix II – Machine design
- Appendix III – Form study
- Appendix IV – List of conditions
- Appendix V – Motor concept
- Appendix VI – Motors and drivers
- Appendix VII – Ratio table of gear transmissions
- Appendix VIII – Design of the control unit
- Appendix IX – Additional parts of the prototype
- Appendix X – Test plan of the CT test
- Appendix XI – Dimensions of the visual model
- Appendix VII – Rules and regulations

# Appendix II - Machine design

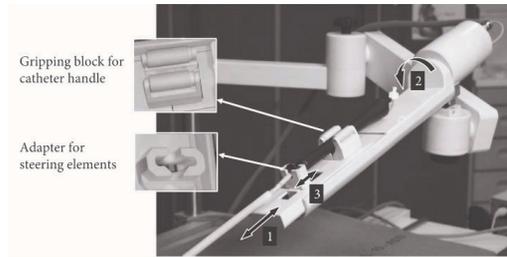


Figure 49. Test setup by Cercelli et al

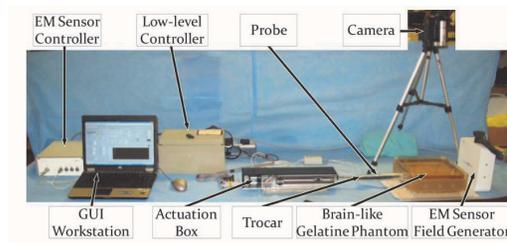


Figure 50. Test setup by Ko et al

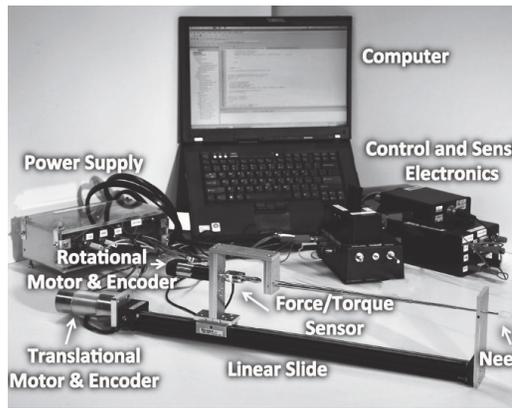


Figure 51. Test setup by Majewicz et al

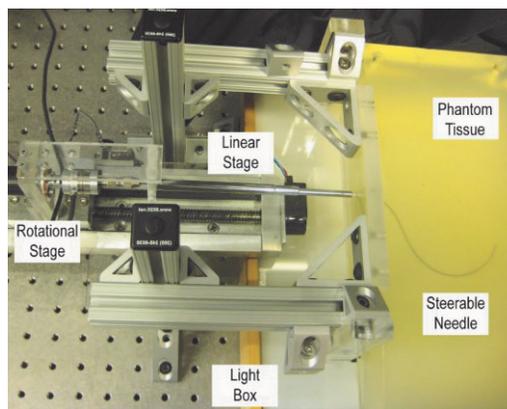


Figure 52. Test setup by Wedlick et al

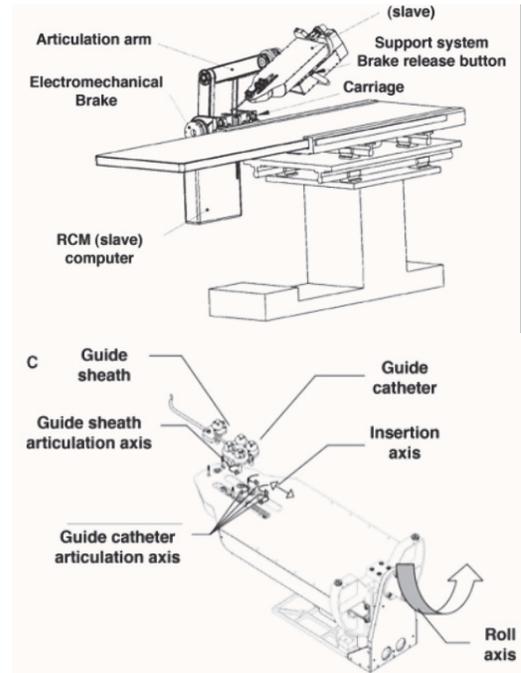


Figure 53. Test setup by Saliba et al

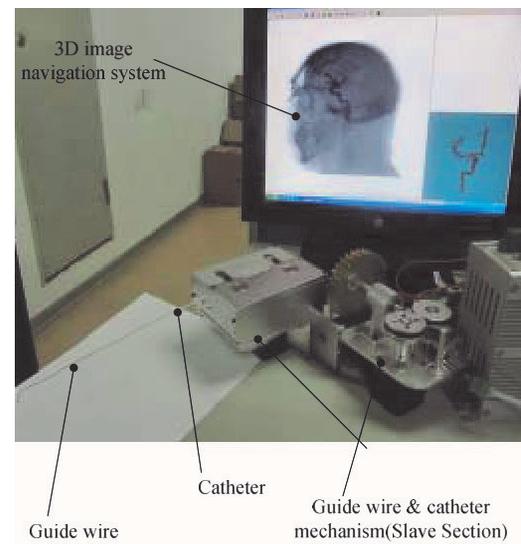


Figure 54. Test setup by Zhang et al

In the figures, all setups and machines from the found literature are presented. The machines from Cerelli et al, Saliba et al and Wang et al (figure 49, 55 and 57) show a product rather than a test setup. Especially in the machine of Saliba et al, a clear distinction is seen between a rotational and linear translation. They are designed as separate entities. The setups of Majewicz and Wedlick (figure 51 and 52) are based on a

linear slider whereupon a rotational encoder is attached. In fact, all setups are designed with the separate entities, except for the setup of Scali et al (figure 55), whose research was mainly about needle design but its setup was inspirational, and for Meng (figure 56), whose machine had both translation integrated in the form of bionic fingers.

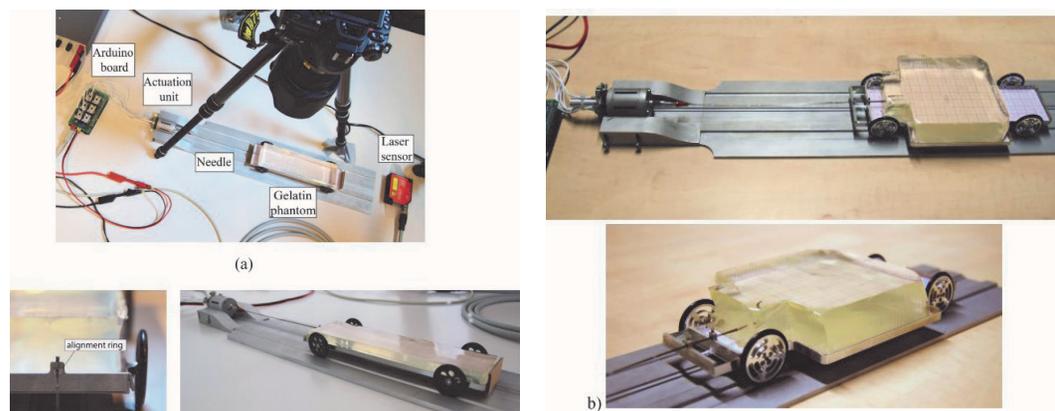


Figure 55. Test setup by Scali et al

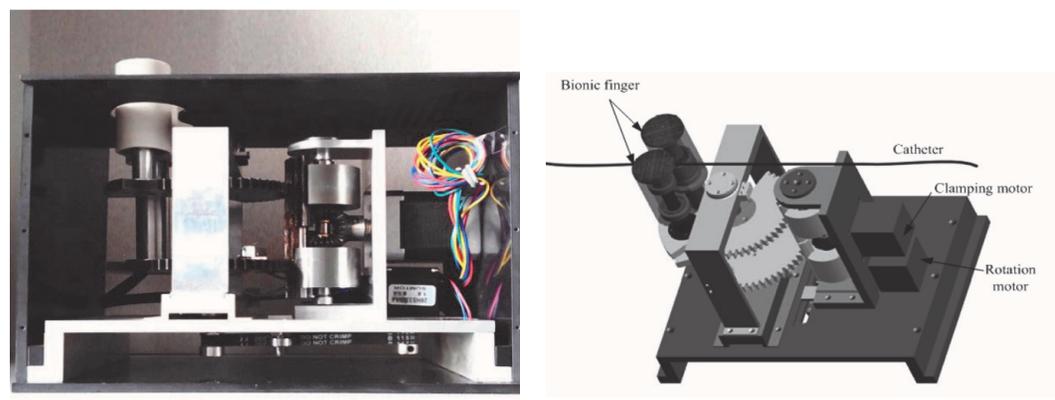


Figure 56. Test setup by Meng

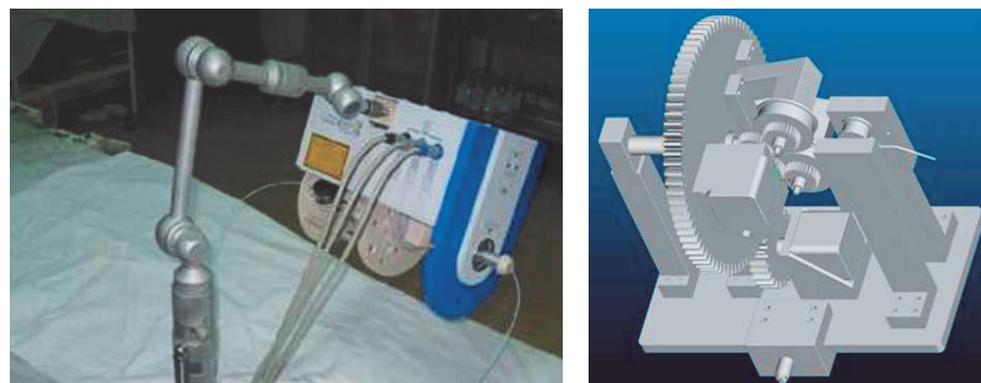


Figure 57. Test setup by Wang et al

# Appendix III - Form study



Figure 58. Baby earmuffs for MRI scanning



Figure 59. Head support for MRI scanning



Support

## 1. Available MR-compatible products

Pumps and monitors



Figure 60. MR-compatible ventilation pump



Figure 61. MR-compatible ventilation pump



Figure 62. MR-compatible ventilator



Figure 63. MR-compatible ventilation pump



Figure 64. Ventilation pump side view

## 2. Overview of products similar to needle control robot

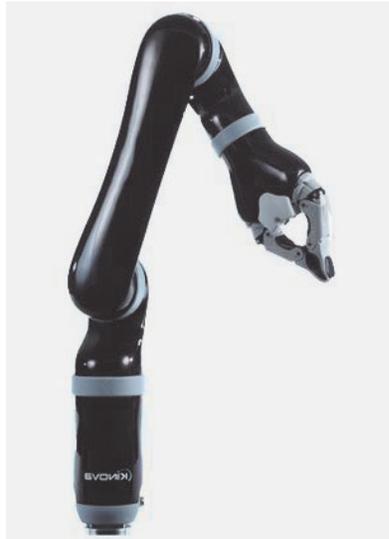


Motor unit



Driver unit

Arms





# Appendix IV - List of conditions

---

A list of conditions is made to define the boundaries of the project and to test the results with the set boundaries afterwards.

## Total device

- The device should be MR-compatible
- The device should fit in an MRI
- The device should be able to be controlled remotely
- The device should hardly be able to move when in use
- The device should be used by medical staff
  - The device should be able to be used by laboratory technicians and physicians
  - The device must be understandable for assisting staff
- The device should be able to connect to the same plug as the RCM
- The appearance of the device should be connected to the RCM

## Motor unit

- The motor should be driven by hydraulic
- The motor should be made from plastic
- The motor should be fixed onto the MR-bed

## Driver unit

- The driver unit should to able to operate different kind of needles
  - The driver should be able to operate needles with diameters of 0,5 to 2,5mm
  - The driver should be able to operate needles with different kinds of surfaces, like rubber or carbon
- The driver should produce a linear and rotational movement
- The driver should be able to fix position on the patient's skin
- The driver should be able to reach all parts of the human skull
- The main dimension of the driver should not be smaller than 5mm
- The main dimension of the driver should not be bigger than 30mm
- The driver should be able to perform a maximum speed of 5mm per second
- The driver should be able to perform a minimum speed of 0,5mm per second
- The driver should be able to perform a maximum step size of 10mm
- The driver should be able to perform a minimum step size of 0,1mm
- The driver should be able to be controlled when in setup phase
- The driver should be able to be controlled remotely
  - The driver should be able to be controlled by manual input
  - The driver should be able to be controlled digitally based on scans
    - The control unit should find a path to follow, based on the MRI scans
    - The control unit should be open to input from the medical staff where the target is
    - The control unit should be open to input from the medical staff what tissue not to hit

#### Needle

- The needle is pre-curved
  - The pre-curved length has a minimum of 150mm
  - The curvature should fit within a diameter of 10-50mm
- The needle is hollow to deliver fluids
- The needle should have a range of 150mm into the body
- The needle should be able to rotate endlessly
- The needle should be accessible for the medical staff to intervene at any moment
- The wire needs 4 DOF's: translational in the X-, Y- and Z-axis and rotational around its inner axis

#### Material

- The material is suitable for medical purpose
- The material is suitable for small parts, which have details of 0,05mm
- The material should be digitally manufactured
- The material should be manufactured for low volume

## Appendix V - Motor concept

In figure 66, the motor concept is seen. The estimation is that it has main dimensions of 100x50x100mm for one motor. The needle control device needs two motors.

The input is air pressure, the output is the yellow ring which rotates. The motor concept will be explained from output to input.

The yellow ring is part of a planetary gear system. A planetary gear system consists of a sun (the center gear), planets (the gear connected to the sun) and the ring which is in this case the yellow ring. A planetary gear simulator is found on the website mekacademy.com (figure 65) which solves the planetary gear system for all number of teeth and desired speed. It is a tool to design the right ratio of gears. The ratio for the motor concept is seen in table 2.

Sun gear	20 teeth
Planet gears	10 teeth
Ring gear	40 teeth

Table 2. number of teeth

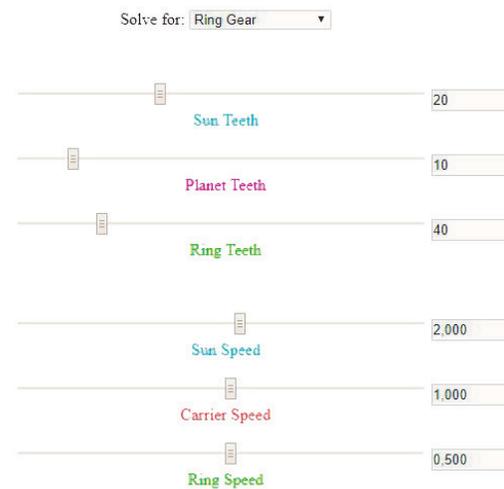
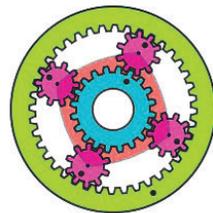


Figure 65. Planetary gear simulator

The RPM of the yellow ring is the result of the RPM of the planets and the RPM of the sun. The advantage of this system is that a high speed is easily reached since both RPM's could be accumulated. But also, a higher accuracy in small steps could be made. For example, if the speed of the sun is 2RPM and the planets are 1RPM, the ring will result in 0,5RPM.

In the motor concept, both are connected to their own sub motor. The sub motor consists of an axis that is driven by two pistons, but the pistons are not centrically aligned with that axis. They differ 90 degrees. When one of the pistons gets a boost from the air pressure, this pistons moves downwards. This moves the other piston and also gets an air pressure boost, resulting in the axis to rotate.

Estimated is that the maximum speed is 120 RPM. It is not known yet what power the gears could have.

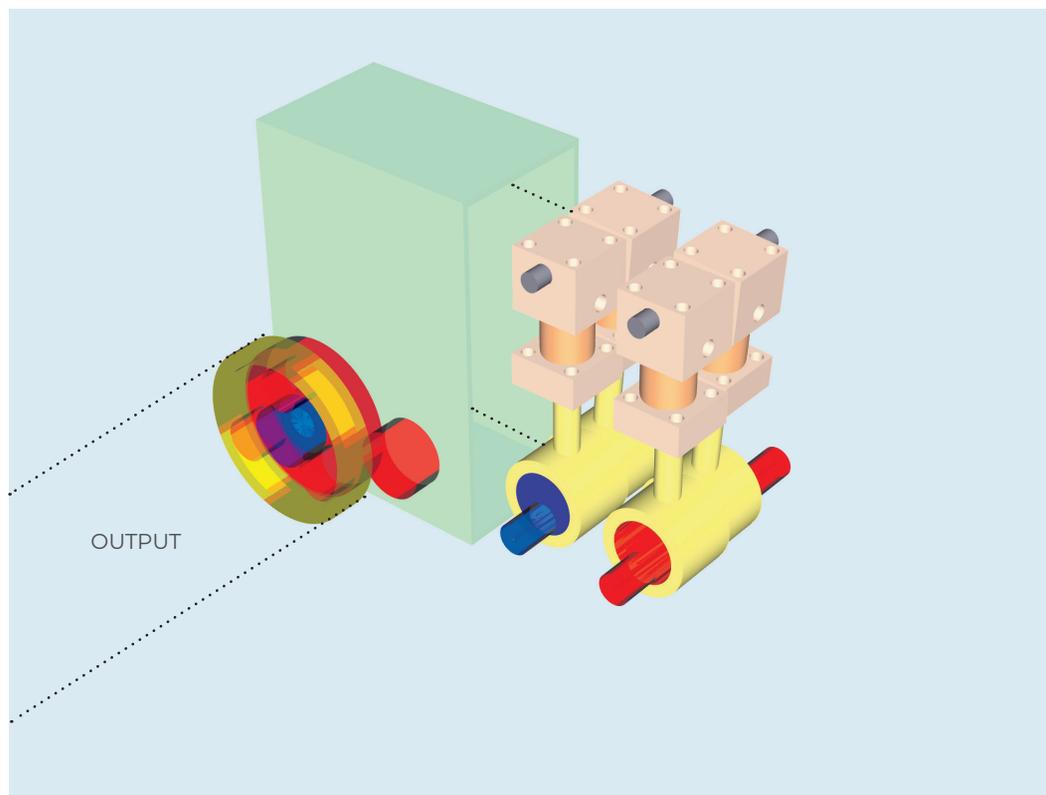


Figure 66. Planetary gear simulator

# Appendix VI - Motors and drivers

In the subsection "Motors" on page 46, the reasoning is given behind the decision of the NEMA 17 and DRV8825. In this appendix, a more in-depth explanation is presented of the difference between the 28BYJ-48 motor and the NEMA 17 and its corresponding drivers.

The 28BYJ-48 is cheap and easy to work with, but has very low torque. It slips easily when you grab the outcoming axis. It is used in many applications like DVD players and security cameras.

The NEMA 17 is a bit more expensive, but is able to continue rotating when you grab the outcoming axis. Of course, this depends on the current that is running through the driver, but it is possible to create a high torque with the NEMA17. In the prototype, the current limit is set at 0,5A (explained in driver paragraph), so the gears will not break when they are locking. In the case of locking, the motor will slip. The NEMA 17 also requires external power, while the 28BYJ-48 could run on the 5V of the Arduino. It is known for its use in 3D printers, CNC machines and laser cutters.



Figure 67. 28BYJ-48



Figure 68. Nema17

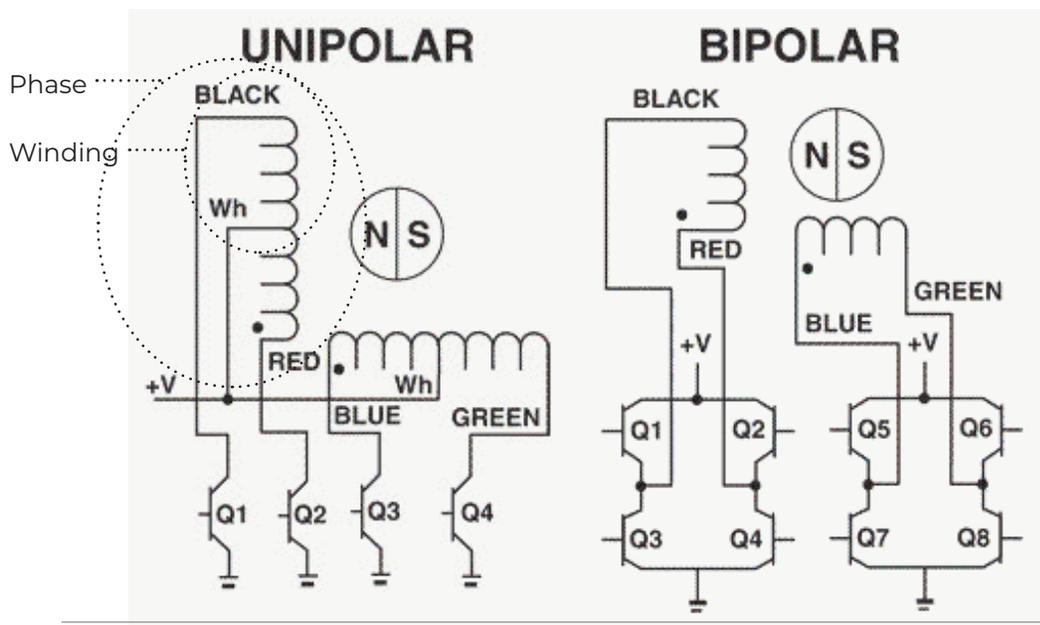


Figure 69. Difference between a unipolar and bipolar stepper

The 28BYJ-48 is a unipolar motor which means that it has multiple windings per phase (see figure 69). With multiple windings, the current has one direction per winding. This makes it easy to control, and therefore the stepper driver is affordable. The NEMA 17 is a bipolar stepper, so one winding per phase and this means that the current needs to drive in both directions. The changing direction of the current makes it harder to control since H-bridges are needed and for unipolar steppers, this is not necessary. But luckily, there are multiple drivers on the market which are still quite affordable.

The difference in appearance is that a unipolar stepper has five wires (could run up to 8 wires), and the bipolar motor has just four wires.

Different drivers have been tested for different motors. In figure 70-73, all drivers are shown.

The L293D H-bridge is a driver that is used for all bipolar steppers and serves as a driver in the Arduino examples. Therefore this driver was bought, but after some research, it was found that the NEMA 17 should be paired with the DRV8825. The 28BYJ-48 steppers are bought in a package together with its ULN2003 drivers. So no conscious choice was made here, but it turned out to work well. Without any further research, the stepper could be connected to Arduino and run. The NEMA 17 however, was a different story: it is harder to connect and caution must be taken in setting the current limit for the DRV8825. Three times, a mistake was made in setting the current limit or placing the driver backward. The result is that the DRV8825 burns and a small plume of smoke arises.

The current limit is defined by the stepper and could be checked with a multimeter and the formula:

$$\text{Current Limit} = V_{\text{ref}} \times 2$$

In the prototype, the current limit is set at 0,25V, so 0,5A.

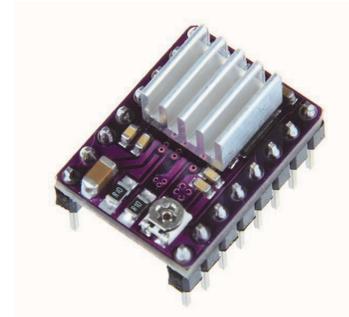


Figure 70. DRV8825



Figure 71. two-axis stepper control driver



Figure 72. L293D H-bridge



Figure 73. ULN2003

Furthermore, the DRV8825 is adjustable for the number of steps. It contains an M0, M1 and M2 port which determine how many steps could be taken. The options for full step,  $\frac{1}{2}$ ,  $\frac{1}{4}$ ,  $\frac{1}{8}$ ,  $\frac{1}{16}$  and  $\frac{1}{32}$  step could be chosen. In table 3, the combination of ports is shown. To adjust the options and play with the accuracy, a switch for M0, M1 and M2 is placed on the PCB for each driver.

At the beginning of the project, also a two-axis stepper control driver was bought. This is a module that includes drivers and is pre-set, but to understand this module and create code, more knowledge on motors and drivers was needed. While finding this knowledge, it was chosen to continue with the separate drivers, since it made the design process more flexible.

M0	M1	M2	Microstep resolution
Low	Low	Low	Full step
High	Low	Low	1/2 step
Low	High	Low	1/4 step
High	High	Low	1/8 step
Low	Low	High	1/16 step
High	Low	High	1/32 step
Low	High	High	1/32 step
High	High	High	1/32 step

Table 3. Microstep resolution table

## Appendix VII - Ratio table of gear transmissions

A ratio table is used to determine all values that are need to be inserted in the software of the control unit. It gave an overview of the impact of changes in gears and the impact of speed and steps. The ratio table is created as an Excel-file to be flexible in adjusting the values (figure 74). The final data that is inserted in the ratio table is shown in table 4. On the next page, the flow of ratios are shown.

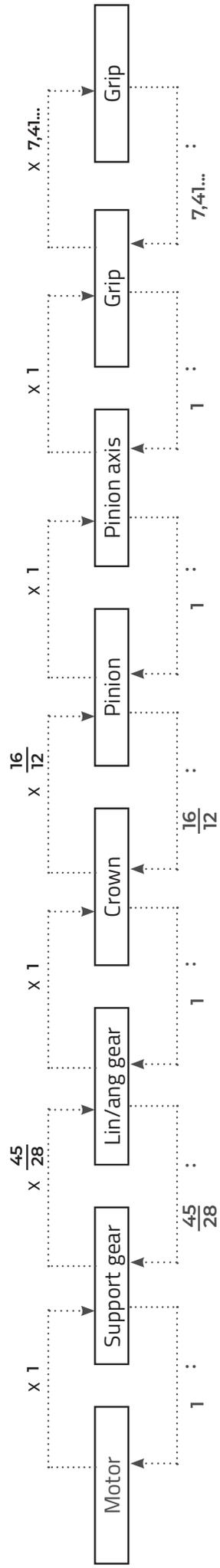
### DATA

<b>Support gear</b>	<b>Module</b>	<b>0,8</b>
	<b>Teeth</b>	<b>45</b>
<b>Lin/ang gear</b>	<b>Module</b>	<b>0,8</b>
	<b>Teeth</b>	<b>28</b>
<b>Crown</b>	<b>Module</b>	<b>0,5</b>
	<b>Teeth</b>	<b>16</b>
<b>Pinion</b>	<b>Module</b>	<b>0,5</b>
	<b>Teeth</b>	<b>12</b>
<b>Pinion axis</b>	<b>Axis radius</b>	<b>1,0</b>
	<b>Axis circumference</b>	<b>6,28...</b>
<b>Grip</b>	<b>Grip radius</b>	<b>1,18</b>
	<b>Grip circumference</b>	<b>7,41...</b>

Table 4. Data of final gears

	A	B	C	D	E	F	G	H	I	J
1		1	2	3	4	5	6	7	8	
2		Motor (RPM)	Tandwiel Overbreng (RPM)	Tandwiel Buiten (RPM)	Tandwiel Binnen crown (RPM)	Tandwiel Binnen pinion (RPM)	As Binnen (RPM)	Grip (RPM)	Verplaatsing draad (mm/minuut)	Verplaatsing draad (mm/sec)
3	Input = motor	120,0	120,0	192,9	192,9	257,1	257,1	257,1	1906,5	31,7749657
4	Input = draad	37,8	37,8	60,7	60,7	80,9	80,9	80,9	600,0	10
5										
6		Motor (graden)	Tandwiel Overbreng (graden)	Tandwiel Bruin Groot (graden)	Tandwiel Bruin Binnen (graden)	Tandwiel Wit Binnen (graden)	As Binnen (graden)	Grip (graden)	Verplaatsing draad (mm)	
7	Input = motor	10,00	10,00	16,07	16,07	21,43	21,43	21,43	0,44	
8	Input = draad	2,3	2,3	3,6	3,6	4,9	4,9	4,9	0,1	
9			3,6							
10	Aantal rotaties	0,01	0,01							
11	Aantal stappen	40	64							

Figure 74. Ratio table from the Excel-file



## Appendix VIII - Control unit

To realize the prototype, the control unit had a more prominent role than expected. During the creation of the assignment, it is stated the focus lays on the driver and the control unit is out of scope. Still, it is an important part of the prototype since it is essential in activating the driver and testing its functionalities.

Creating the prototype started with setups and codes in Arduino where different motors and drivers are used (figure 75 and 76).

After the decision of which motor and driver to use, an initial prototype is created with one potentiometers (figure 77), later on it expanded to two potmeters for two motors (figure 78). An adaption of the example code "Stepper speed control" is used to drive the motors. Although the prototype worked as expected, the potmeter created a lot of noise and therefore, the speed was not constant.

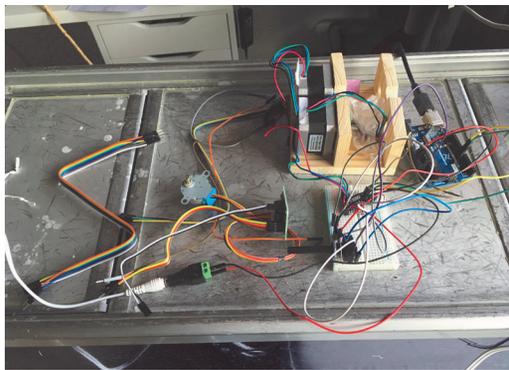


Figure 75. Experimenting with different motors and drivers

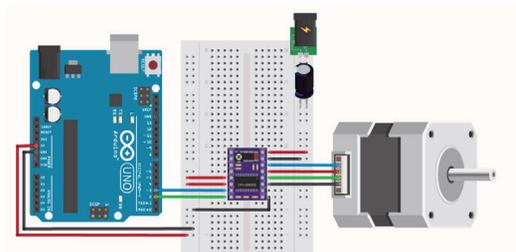


Figure 76. Scheme of the right motor and driver

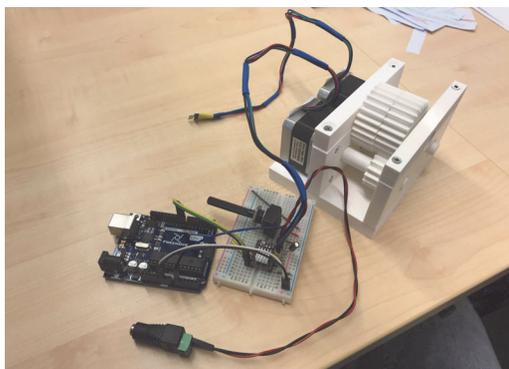


Figure 77. Explorations with one motor

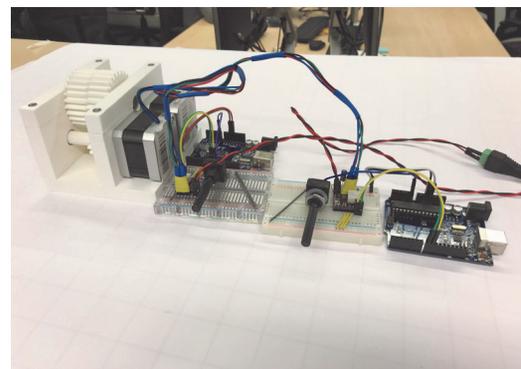
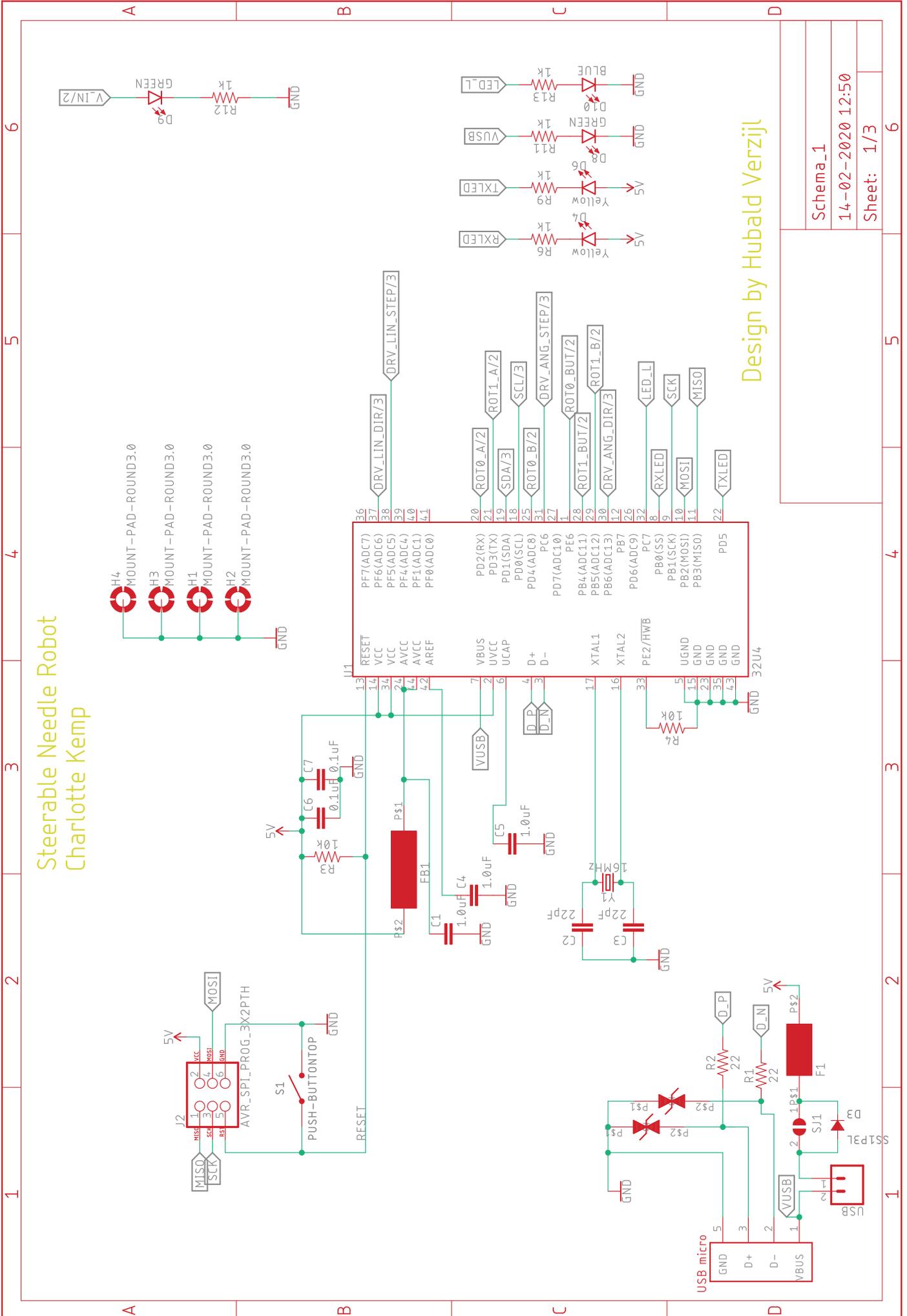


Figure 78. Prototype with two active motors



# Steerable Needle Robot Charlotte Kemp



Design by Hubald Verzijl

Schema\_1

14-02-2020 12:50

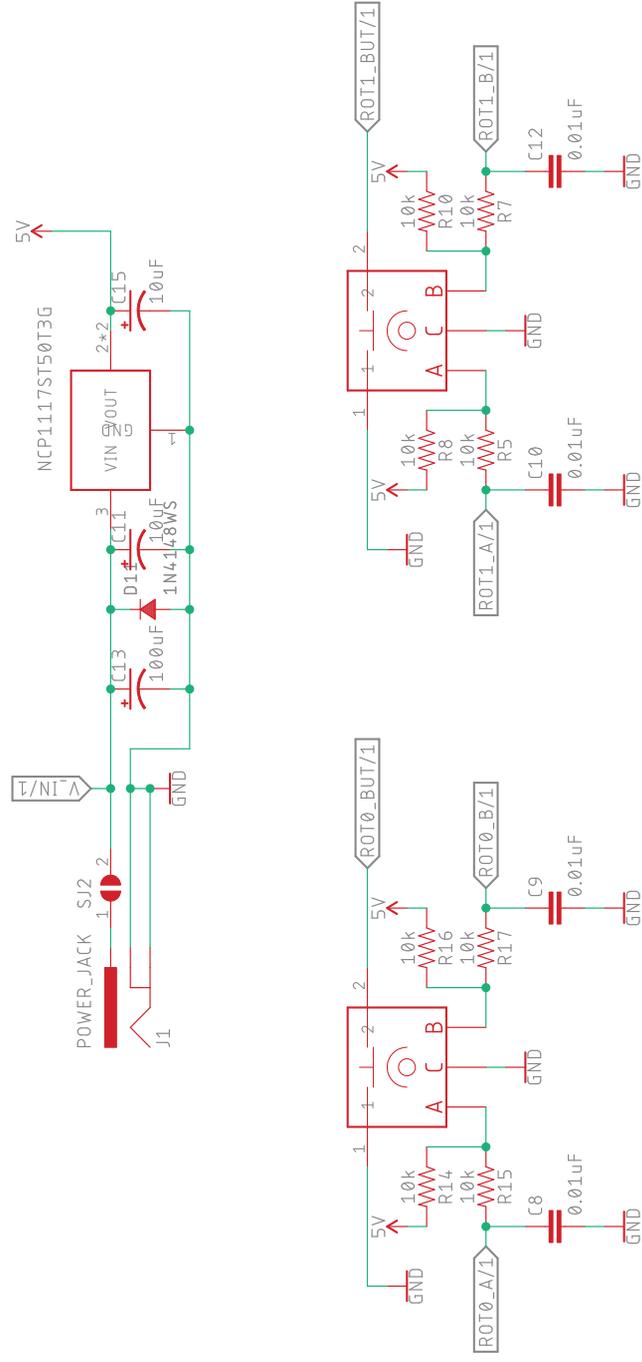
Sheet: 1/3

A

B

C

D



Design by Hubald Verzijl

Schema\_1

14-02-2020 12:50

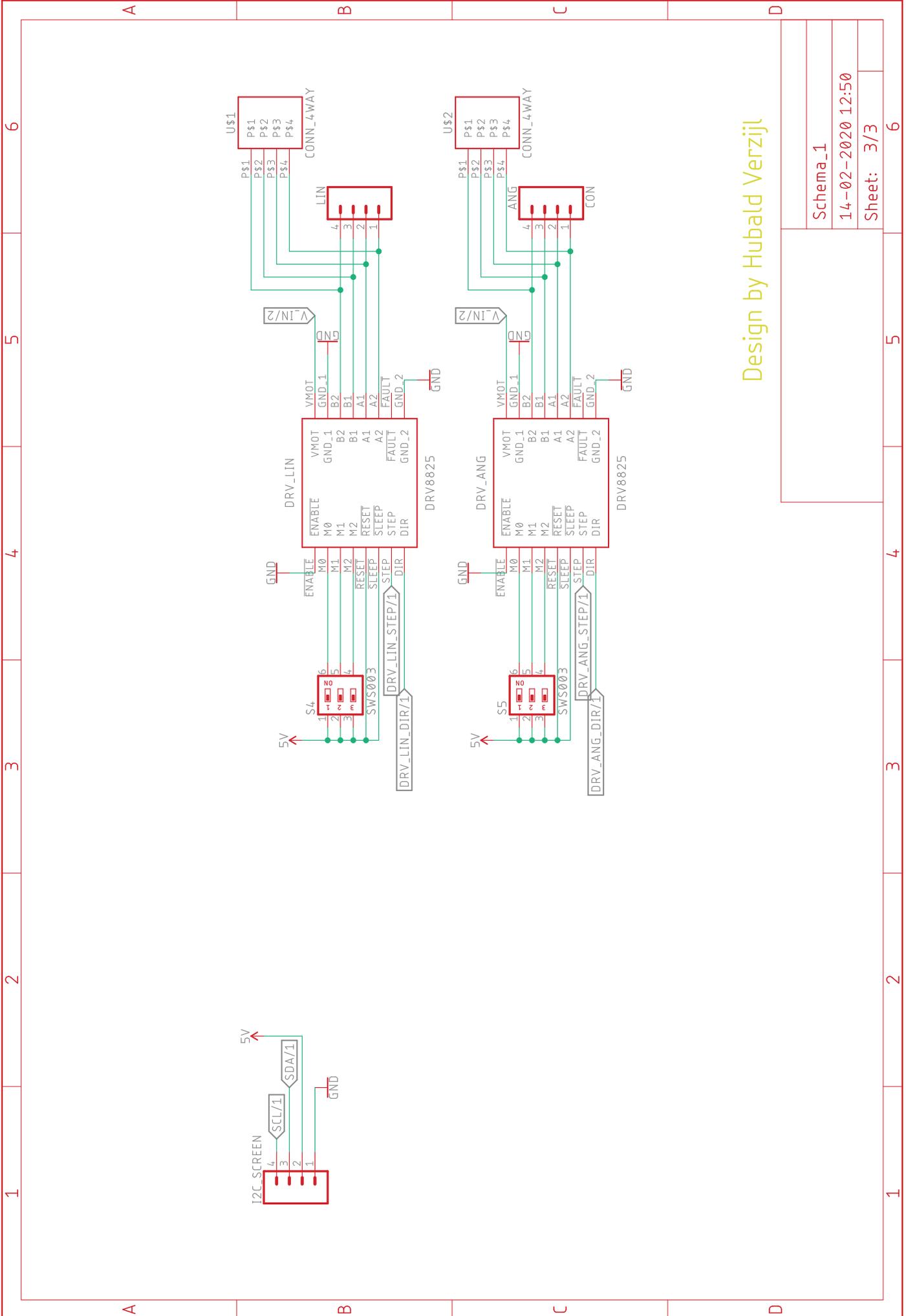
Sheet: 2/3

A

B

C

D



Design by Hubald Verzijl

Schema\_1

14-02-2020 12:50

Sheet: 3/3

```

1  /* Software for the Needle Steering Robot
2  Written by Hubald Verzijl
3  01/2020
4  */
5
6  #include <Arduino.h>
7  #include <Wire.h>
8  #include <LiquidCrystal_I2C.h>
9  #include <AccelStepper.h>
10 #include <MultiStepper.h>
11 #include <avr/io.h>
12
13 #define encoderLinPosPinA 4
14 #define encoderLinPosPinB 0
15
16 #define encoderAngPosPinA 9
17 #define encoderAngPosPinB 1
18
19 #define dirLinPin A1
20 #define stepLinPin A2
21
22 #define dirAngPin 10
23 #define stepAngPin 5
24
25 #define motorInterfaceType 1
26
27 #define selectLinPin 7
28 #define selectAngPin 8
29
30 bool selectLinPressed;
31 bool selectAngPressed;
32
33 long encoderLinPos = 0;
34 long stepperLinPos = 0;
35 long encoderAngPos = 0;
36 long stepperAngPos = 0;
37 long encoderDltPos = 0;
38
39 unsigned long currentMillis = 0;
40 unsigned long previousMillisLED = 0;
41 unsigned long previousMillisScreen = 500;
42
43 // Rotary encoder lin
44 static uint8_t prevNextCodeLin = 0;
45 static uint16_t storeRotPosLin = 0;
46
47 // Rotary encoder ang
48 static uint8_t prevNextCodeAng = 0;
49 static uint16_t storeRotPosAng = 0;
50

```

```

51 // Initiate LCD
52 LiquidCrystal_I2C lcd(0x27, 16, 2);
53
54 // Initiate Stepper(s)
55 AccelStepper stepperLin = AccelStepper(motorInterfaceType,
stepLinPin, dirLinPin);
56 AccelStepper stepperAng = AccelStepper(motorInterfaceType,
stepAngPin, dirAngPin);
57
58 MultiStepper steppers;
59
60 // Define functions
61 int8_t readRotaryLin();
62 int8_t readRotaryAng();
63
64 void readSelectButtons();
65 void runHand();
66 void runPC();
67 void runDriving();
68
69 long mod(long a, long b);
70
71 // States of the system
72 enum states{
73 START,
74 PC,
75 HAND,
76 DRIVING,
77 };
78 enum states state = START;
79
80 // Define variables
81 int gainPosStep = 40; // # of stepper motor steps for
every rotary encoder step
82 int gainAngStep = 11;
83
84 int angleCircle = 360; // TODO: later naar 360
85
86 long positions[2]; // Stepper motor positions
87
88 void setup() {
89
90 Wire.begin(); // I2C
91
92 // Input definitions
93 pinMode(encoderLinPosPinA, INPUT);
94 pinMode(encoderLinPosPinB, INPUT);
95
96 pinMode(encoderAngPosPinA, INPUT);
97 pinMode(encoderAngPosPinB, INPUT);

```

```

98
99  pinMode(selectLinPin, INPUT_PULLUP);
100  pinMode(selectAngPin, INPUT_PULLUP);
101
102  pinMode(dirLinPin, OUTPUT);
103  pinMode(stepLinPin, OUTPUT);
104
105  pinMode(dirAngPin, OUTPUT);
106  pinMode(stepAngPin, OUTPUT);
107
108  Serial.begin(9600); // Serial monitor
109
110  // LCD init
111  lcd.init();
112  lcd.backlight();
113  lcd.setCursor(0,0);
114
115  // Define maximum speed and accelerations steppers
116  stepperLin.setMaxSpeed(6400);
117  stepperLin.setAcceleration(100000);
118  stepperLin.setCurrentPosition(0);
119
120  stepperAng.setMaxSpeed(6400);
121  stepperAng.setAcceleration(100000);
122  stepperAng.setCurrentPosition(0);
123
124  steppers.addStepper(stepperLin);
125  steppers.addStepper(stepperAng);
126
127  pinMode(LED_BUILTIN, OUTPUT);
128
129  // TCCR1A = 0; // normal operation
130  // TCCR1B = bit(WGM12) | bit(CS10) | bit(CS12); //
    CTC, scale to clock / 1024
131  // OCR1A = 999; // compare A register value (
    1000 * clock speed / 1024)
132  // TIMSK1 = bit(OCIE1A); // interrupt on
    Compare A Match
133  // interrupts();
134 }
135
136 void loop() {
137
138  readSelectButtons(); // Read rotary encoder
    buttons
139
140  // Create menu
141  if ( selectLinPressed || selectAngPressed || state ==
    START) {
142      if (selectAngPressed) {

```

```

143  if (state == DRIVING) {
144      stepperLinPos += encoderLinPos*
    gainPosStep;
146  stepperLin.setSpeed(15000);
147  stepperAng.setSpeed(15000);
148
149  stepperLinPos = stepperLin.currentPosition
    ();
150
151  positions[0] = stepperLinPos;
152  steppers.moveTo(positions);
153  steppers.runSpeedToPosition();
154
155  stepperAng.setSpeed(0);
156  stepperLin.setSpeed(0);
157
158  state = HAND;
159  lcd.clear();
160  lcd.setCursor(0,0);
161  lcd.print("Mode: MANUAL");
162  lcd.setCursor(0,1);
163  lcd.print("Pos:");
164  lcd.print(stepperLinPos);
165  lcd.setCursor(8,1);
166  lcd.print(" Ang:");
167  lcd.print(stepperAngPos);
168
169  } else {
170      state = DRIVING;
171      lcd.clear();
172      lcd.setCursor(0,0);
173      lcd.print("Mode: DRIVING");
174      lcd.setCursor(0,1);
175      lcd.print("Rotate lin knob");
176      stepperAng.setSpeed(6400);
177      stepperLin.setSpeed(6400);
178
179  }
180
181  if (selectLinPressed || state == START) {
182      switch (state) {
183          case START:
184              state = PC;
185              lcd.clear();
186              lcd.setCursor(0,0);
187              lcd.print("Select a mode");
188              break;
189          case PC:
190              state = HAND;
191              lcd.clear();
192              lcd.setCursor(0,0);

```

```

191 lcd.print("Mode: MANUAL");
192 lcd.setCursor(0,1);
193 lcd.print("Rotate a knob!");
194 break;
195 case DRIVING:
196 stepperLinPos += encoderLinPos*
197 gainPosStep;
198 //
199 steppers.runSpeedToPosition();
200 stepperAng.setSpeed(0);
201 stepperLin.setSpeed(0);
202
203 state = HAND;
204 lcd.clear();
205 lcd.setCursor(0,0);
206 lcd.print("Mode: MANUAL");
207 lcd.setCursor(0,1);
208 lcd.print("Pos:");
209 lcd.print(encoderLinPos);
210 lcd.setCursor(8,1);
211 lcd.print(" Ang:");
212 lcd.print(encoderAngPos);
213 break;
214 case HAND:
215 state = PC;
216 lcd.clear();
217 lcd.setCursor(0,0);
218 lcd.print("Mode: DIGITAL");
219
220 Serial.println("Send pos-ang value!");
221 break;
222 default:
223 break;
224 }
225 }
226
227 // Wait until button is released
228 while (selectLinPressed || selectAngPressed) {
229   readSelectButtons();
230 }
231 delay(100);
232 }
233
234 // Choose the correct function to execute
235 switch (state) {
236 case PC:
237   runPC();
238   break;
239 case HAND:

```

```

240 runHand();
241 break;
242 case DRIVING:
243   runDriving();
244   break;
245 default:
246   break;
247 }
248
249 }
250
251 // Run by hand
252 void runHand() {
253   // Read rotary encoder
254   int8_t resultLin = readRotaryLin();
255   int8_t resultAng = readRotaryAng();
256
257   // If rotary encoder has moved, add gain*number of
258   // steps to location of stepper motor
259   if ((resultLin != 0) || (resultAng != 0)) {
260     if (resultLin != 0) {
261       encoderLinPos += resultLin;
262       stepperLinPos += gainPosStep*resultLin;
263     }
264
265     if (resultAng != 0) {
266       encoderAngPos += resultAng;
267       stepperAngPos += gainAngStep*resultAng;
268       stepperLinPos += gainAngStep*resultAng;
269     }
270
271     if (encoderAngPos == angleCircle && (resultAng == 1
272     )) {
273       encoderAngPos = 0;
274     } else if (encoderAngPos == -1 && (resultAng == -1
275     )) {
276       encoderAngPos = angleCircle-1;
277     }
278
279     // Print the result on LCD
280     lcd.clear();
281     lcd.setCursor(0,0);
282     lcd.print("Mode: MANUAL");
283     lcd.setCursor(0,1);
284     lcd.print("Pos:");
285     lcd.print(encoderLinPos);
286     lcd.setCursor(8,1);
287     lcd.print(" Ang:");
288     lcd.print(encoderAngPos);

```

```

287
288 // Move the stepper motors together
289 positions[0] = stepperLinPos;
290 positions[1] = stepperAngPos;
291
292 steppers.moveTo(positions);
293
294 }
295
296 steppers.run();
297
298 void runPC() {
299 // If serial input signal is available, read input
300 if (Serial.available() ) {
301 delay(50);
302
303 char input_char;
304 String input_string = "";
305
306 int inputPos = 0;
307 int inputAng = 0 ;
308
309 while (Serial.available()) {
310 input_char = (char) Serial.read();
311 input_string.concat(input_char);
312
313 }
314
315 int posBar = input_string.indexOf('-');
316 if (posBar > 0) {
317 inputPos = (int) input_string.substring(0, (
318 inputPos).toInt());
319 inputAng = (int) input_string.substring((
320 inputPos).toInt()).toInt();
321 }
322
323 // Input angle to simplified angle
324 inputAng = (int) mod(inputAng, angleCircle);
325
326 // Print recieved values
327 Serial.print("Rec:");
328 Serial.print(inputPos);
329 Serial.print("-");
330 Serial.println(inputAng);
331
332 // Add the steps to the positions of the steppers
333 stepperLinPos += (inputPos-encoderLinPos)*
gainPosStep;
334
335 stepperAngPos += (inputAng-encoderAngPos)*
gainAngStep;

```

```

333 gainAngStep;
334 stepperLinPos += (inputAng-encoderAngPos)*
gainAngStep;
335
336 if ((encoderAngPos-inputAng) > (0.5 * angleCircle))
{
337 stepperAngPos += angleCircle*gainAngStep;
338 stepperLinPos += angleCircle*gainPosStep;
339 }
340
341 encoderLinPos = inputPos;
342 encoderAngPos = inputAng;
343
344 // Move the stepper motors together
345 positions[0] = stepperLinPos;
346 positions[1] = stepperAngPos;
347
348 steppers.moveTo(positions);
349
350 }
351
352 steppers.run();
353
354 void runDriving() {
355 int8_t resultLin = readRotaryLin();
356
357 currentMillis = millis();
358
359 // If rotary encoder rotated, change future position
360 if (resultLin != 0) {
361
362 if (encoderDltPos >= 3) {
363 resultLin = 0;
364 } else if (encoderDltPos <= -3) {
365 resultLin = 0;
366 } else {
367 digitalWrite(LED_BUILTIN, HIGH);
368 }
369
370 previousMillisLED = currentMillis;
371
372 encoderLinPos += resultLin;
373 encoderDltPos += resultLin;
374
375 }
376
377 if (currentMillis - previousMillisScreen >= 5000) {
378 previousMillisScreen = currentMillis;
379 // Show input
380 lcd.clear();

```

```

381 lcd.setCursor(0,0);
382 lcd.print("Mode: DRIVING");
383 lcd.setCursor(0,1);
384 lcd.print("Pos:");
385 lcd.print(encoderLinPos);
386 }
387
388 if (currentMillis - previousMillisLED >= 25) {
389   digitalWrite(LED_BUILTIN, LOW);
390 }
391
392 // After one round, set new location at the end of the
   next round
393   if (stepperAng.currentPosition() >= positions[1]) {
394
395     stepperLin.setSpeed(3200 + encoderDltPos*1000);
396     stepperAng.setSpeed(3200);
397
398     stepperAngPos += angleCircle * gainAngStep;
399     positions[0] = stepperLinPos;
400     positions[1] = stepperAngPos;
401     encoderDltPos = 0;
402     Serial.print(stepperLinPos);
403     Serial.print("-");
404     Serial.println(stepperAngPos);
405   }
406   stepperLin.runSpeed();
407   stepperAng.runSpeed();
408 }
409
410 // Read rotary encoder
411 int8_t readRotaryLin() {
412   prevNextCodeLin <=< 2;
413   if (digitalRead(encoderLinPosPinA)) prevNextCodeLin |=
0x02;
414   if (digitalRead(encoderLinPosPinB)) prevNextCodeLin |=
0x01;
415   prevNextCodeLin &= 0x0f;
416
417   // If valid then store as 16 bit data.
418
419   //static uint8_t rot_enc_table[] = {0, 1, 1, 0, 1, 0, 1, 0,
1, 1, 0, 0, 1, 1, 0, 1, 1, 0};
420   static uint16_t rot_enc = 0b01101001110010110; //
0b01101001110010110
421
422   if ((rot_enc >> prevNextCodeLin) & 0x01) {
423     storeRotPosLin <=< 4;
424     storeRotPosLin |= prevNextCodeLin;
425     //if (store==0xd42b) return 1;

```

```

426 //if (store==0xe817) return -1;
427   if ((storeRotPosLin & 0xff) == 0x2b) return -1;
428   if ((storeRotPosLin & 0xff) == 0x17) return 1;
429 }
430 return 0;
431 }
432
433 int8_t readRotaryAng() {
434   prevNextCodeAng <=< 2;
435   if (digitalRead(encoderAngPosPinA)) prevNextCodeAng |=
0x02;
436   if (digitalRead(encoderAngPosPinB)) prevNextCodeAng |=
0x01;
437   prevNextCodeAng &= 0x0f;
438
439   // If valid then store as 16 bit data.
440
441   //static uint8_t rot_enc_table[] = {0, 1, 1, 0, 1, 1, 0, 1, 0,
1, 1, 0, 0, 1, 1, 0, 1, 1, 0};
442   static uint16_t rot_enc = 0b01101001110010110; //
0b01101001110010110
443
444   if ((rot_enc >> prevNextCodeAng) & 0x01) {
445     storeRotPosAng <=< 4;
446     storeRotPosAng |= prevNextCodeAng;
447     //if (store==0xd42b) return 1;
448     //if (store==0xe817) return -1;
449     if ((storeRotPosAng & 0xff) == 0x2b) return -1;
450     if ((storeRotPosAng & 0xff) == 0x17) return 1;
451   }
452   return 0;
453 }
454
455 long mod(long a, long b)
456 {
457   // Create modulo function, in C % it is a remainder
   function
458   long r = a % b;
459   return r < 0 ? r + b : r;
460 }
461
462 void readSelectButtons() {
463   // Read buttons
464   digitalWrite(selectLinPin) == LOW ? (selectLinPressed =
true) : (selectLinPressed = false);
465   digitalWrite(selectAngPin) == LOW ? (selectAngPressed =
true) : (selectAngPressed = false);
466 }
467
468

```



# Appendix IX - Additional parts of the prototype

## Housing

The housing evolved according to the chosen motors and gears. The first iterations are illustrated by a wooden housing (figure 80 and 81). This was chosen to make fast alternations and is easy to work with.

When the right dimensions are found, a PLA version is made (figure 82 and 83). This is more stiff housing and fits the motor and driver better.

Finally, the complete prototype is made into its final shape. A transparent appearance is chosen to present the driver and have a clear view. Before the transparent Perspex is sent to the laser cutter, a wooden version is made to check if it all fits (figure 84). A few remarks are corrected in the Illustrator-file and the final version is sent to the laser cutter. With Acrifix – the Perspex adhesive, the prototype is assembled (figure 85-87).

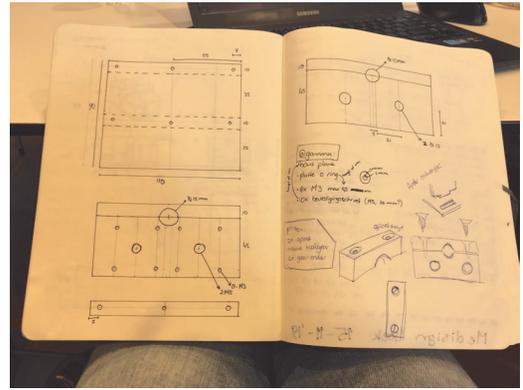


Figure 80. First idea of prototype

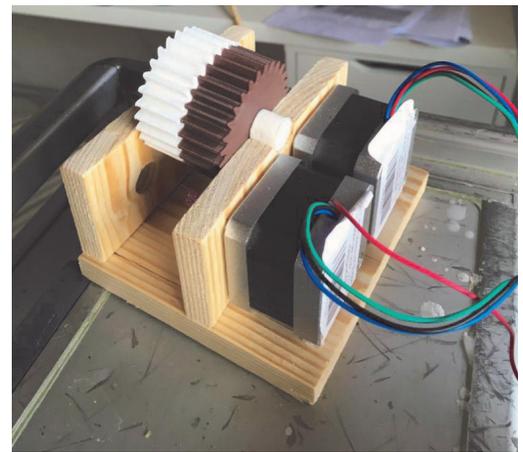


Figure 81. Wooden housing

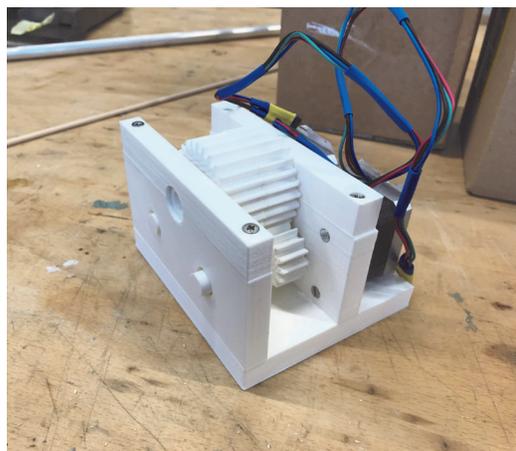


Figure 82. PLA housing

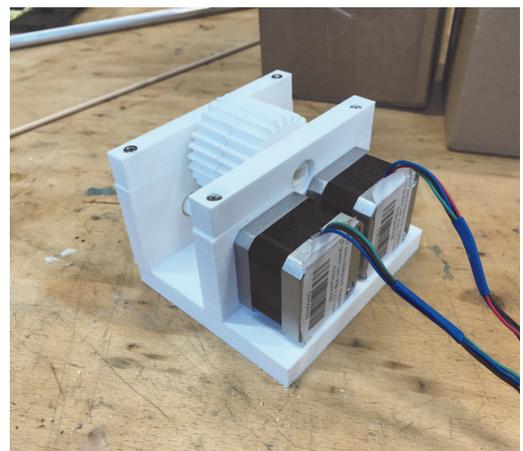


Figure 83. PLA housing

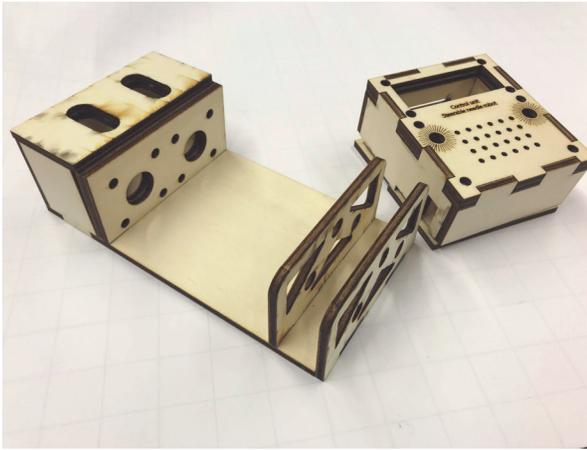


Figure 84. Wooden housing of the final prototype



Figure 85. Fixing all Perspex parts with Acrifix

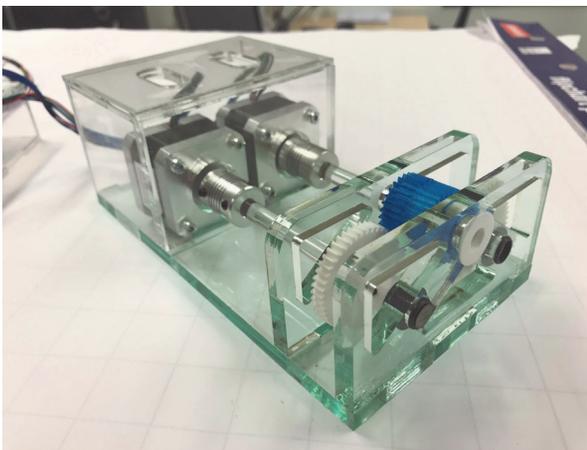


Figure 86. PLA housing motor and driver

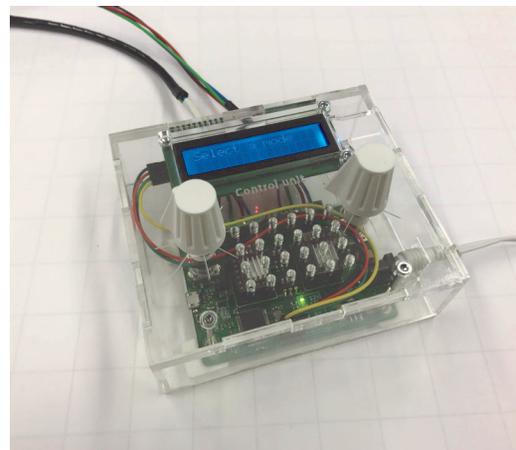


Figure 87. PLA housing control unit

## Motor coupling

A distance between the driver and motors is desired to keep the motors away from the scan plane in the CT. To bridge the distance, the support gears are driven by two transparent rods that are connected to the motors.

This connection is established by two motor couplings. Next to connecting the rods with the motors, it takes care of any dislocation of the two axes.



Figure 88. Motor coupling

### Needle

The needle is an angiographic catheter which has expired its sterility date. The length is 1m and the size is 5F (French, which corresponds with 1,67mm). It has no side holes and could take max. 1200psi. Two needles have been made available for testing.

This needle is a good option since it is flexible and has a pre-curved tip. Cutting the needle into parts of 0,4m results in one part that has a pre-curved tip and the rest is straight. By bending the straight parts around a rod and expose it to a heat gun, the needles are curved. In figure 89, the curved needles are shown.

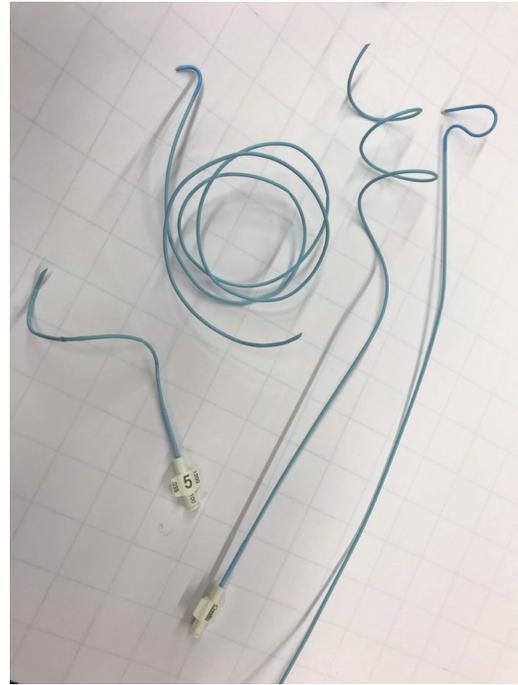


Figure 89. Needles

### Bearing with Luer Lock

For the transparent rods, standard bearings are ordered. For the driver, two bearings are designed and printed with the FDM 3D-printer. These bearing have two functions: enable the rotations in the prototype and keeping the driver in place. One of the bearings is a regular bearing with a cut-out to keep the driver in place. The other bearing has the same cut-out, but also has a female connection of the Luer lock integrated. With this Luer lock, all medical connectors could be attached to the bearing and therefore, to the prototype. In figure 90, the technical drawing of a female connection of the Luer lock is presented. Figure 91 and 92 show the final bearing.

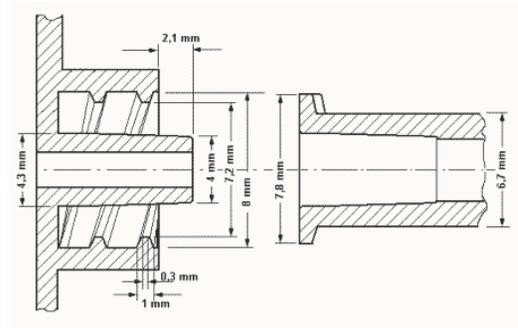


Figure 90. Schematic intersection of dimensions

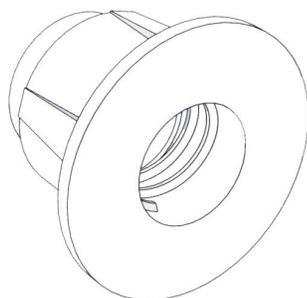


Figure 91. Bearing with Luer lock

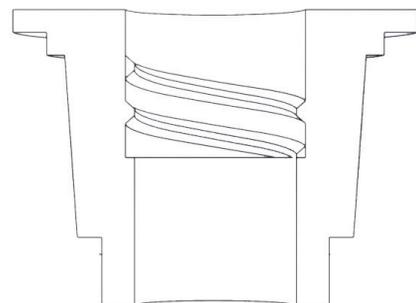


Figure 92. Intersection of the bearing

# Appendix X - Test plan

---

## Doel van testen:

*Functioneel prototype (proof of principle):* de functie van de tandwielen checken op verwachtingen en testen of dit ook te zien is op scans. Zo goed mogelijk het nieuwe scenario testen op functionaliteit.

*Visueel model (final design proposal):* gebruiksvriendelijkheid testen door nieuw scenario te doorlopen met laborant(en). Tips krijgen van gebruikers hoe bepaalde handelingen moeten lopen, hoe vast te maken aan het bed, hoe te bedienen, hoe het eruit moet zien.

## Verwachtingen:

*Functioneel prototype:*

In het gunstigste geval klemt de driver de draad in en kan het de draad door de gel sturen zonder te slippen. Het scherm op de control unit geeft de positie en hoek aan en op de scans van de CT is dit ook te zien. Ook de digitale modus werkt en met een bepaalde string aan codes kan het prototype de draad naar een bepaalde locatie sturen. Van de scans wordt een filmpje gemaakt waardoor er in het transversale vlak geopereerd moet worden.

In het slechtste geval pakt de driver de draad niet en wordt de draad niet bestuurt/de draad slipt. Ook zou het kunnen dat de voerbuis niet op het prototype past. Het zou kunnen dat de draad te stijf is en niet door de voerbuis wil of zich niet laat sturen in de gel. Het kan ook gebeuren dat de gel niet wil blijven liggen.

Het zou jammer zijn als de draden tussen de motor en control unit contact verliezen en daardoor de control unit in de CT ruimte moet staan. Het kan wel, maar het zou jammer zijn. Net als wanneer de driver de draad niet pakt, dan zouden de filmpjes met de hand gemaakt moeten worden.

Alles is voorbereid voor het gunstigste geval, maar ter plekke kunnen er dingen misgaan. Daarvoor zijn er extra driver tandwielen besteld en extra lagers die bevestigd moeten worden aan de voerbuis.

*Visueel model:*

De verwachting is dat er veel aan te merken is op de manier waarop ik denk dat het product gebruikt zal worden. De tips zullen bruikbaar zijn om een herontwerp te maken of desnoods aanbevelingen voor het ontwerp.

## Plaats en tijd:

Radboudumc, Nijmegen op dinsdag 14 januari om 17:00. Eindtijd niet bekend, maar naar verwachting duurt het tot 18:00-18:30. Precieze locatie is de CT scanner met de control ruimte erbij.

## Aanwezigen:

Charlotte Kemp, Dennis Bosboom, 1 of 2 laborant(en). Voertaal is Nederlands

## Middelen:

<i>Het functionele prototype:</i>	base met tandwielen, control unit, kabels, naalden, gel (meerdere exemplaren)
<i>Het visueel model:</i>	3D prints en eventueel tekeningen, scenario uitgeprint
Middelen om vast te leggen:	(opgeladen en lege) Camera van service desk, statief, geluidrecorder op telefoon, opgeladen powerbank, notitieboek, pennen, laptop, oplader, muis, bedankje laborant(en)
Reserve onderdelen:	extra tandwielen, lagers, draad, schroeven, inbussleutels, schroevendraaiers

## Setup:

### *Functioneel prototype:*

Op het bed van de CT scanner wordt het prototype gelegd. Het prototype is zwaar genoeg om stabiel te blijven staan. Alle tandwielen en lagers worden op hun plaats gebracht en de voerbuis met luerlock wordt aangesloten op de base. De naald kan als testje in de voerbuis gebracht worden voordat de driver tandwielen geplaatst zijn, om te voelen hoeveel druk de 90 graden bocht geeft. Nadat het prototype gereed is gemaakt, kan de gel geplaatst worden aan de voerbuis. Daarnaast wordt de control unit in de control ruimte geplaatst en de kabels worden gekoppeld. Het prototype is klaar voor gebruik.

### *Visueel model:*

De 3D geprinte onderdelen worden in elkaar geschroefd, strak genoeg dat het niet uit elkaar valt, maar er nog wel gedraaid kan worden. Geluidsrecorder aan. Notitieboek met pennen open.

## Methode:

### *Functioneel prototype:*

Het bed wordt in de CT geschoven, net zo ver tot de driver wel in het scanvlak ligt, maar de motors en assenkoppeling niet. De CT gaat scannen terwijl ik/Dennis via de control unit de drivers aanstuur. Als het goed gaat, wordt de draad dan door de gel geleid. De CT scans worden opgeslagen als filmpje. De eerste keer zal ik aan de knoppen zitten, een tweede keer Dennis zodat ik kan filmen. Er moet dus minstens 2x gescand worden, maar ik verwacht meerdere keren om een optimaal filmpje te krijgen. Na het testen in de CT, wil ik het visueel model testen met Dennis en de laboranten. De test van het functionele prototype gaat voor.

### *Visueel model:*

Informeel interview met laborant(en). Als eerst uitleggen dat er een informeel interview wordt gehouden en of de geluidsrecorder aan mag, zodat ik niet hoeft mee te schrijven. Wel ligt mijn notitieblok klaar, als ik toch een kleine aantekening wil maken of iets wil tekeningen voor extra uitleg. Met hem/haar/hen loop ik het voorlopige gebruikersscenario door en hoor alle op-/aanmerkingen aan. Vragen die ik stel:

- Wat is jullie eerste indruk?
- Hoe zou je het anders doen?
- Hoe kan het veiliger, makkelijker, betrouwbaarder?



## Result of the CT test

---

The CT test is not strictly executed like planned. Some parts went different than stated in the test plan and in this appendix, an overview is given of that day.

The preparations for the test started at 16:30u on the 30th of January. Dennis and I came went to the control room of the CT and saw that there was still an intervention going on. A patient was laying on

the CT bed and approximately eight members of the medical staff were there. Dennis and I watched and prepared test.

When the intervention was done, Dennis asked a laboratory technician to stay for our test. He could stay for a little while to help, but couldn't stay long. So we rushed to get the setup ready. Unfortunately, some aspects did not work.



Figure 93. Adding tape

The tip of the prepared needle was too rigid, so another needle could be used but needed tape. The number of layers tape also varied so it was hard to find a balance in the thickness of the needle to make it work. After some repetition, the right thickness was found.

Suddenly, one motor did not work. This has never happened at the TU before, so it was a new problem. By twisting the motor coupling, it was found that one motor did have any current. By switching the cables, it was excluded that there was something wrong with the motor. Also, the stepper drivers on the PCB were not hot, so they were still working. It had to do with the connection between the PCB and the cables. By unscrewing the cables and fastening them again, it worked. Still, no idea what was wrong. This situation happened twice.

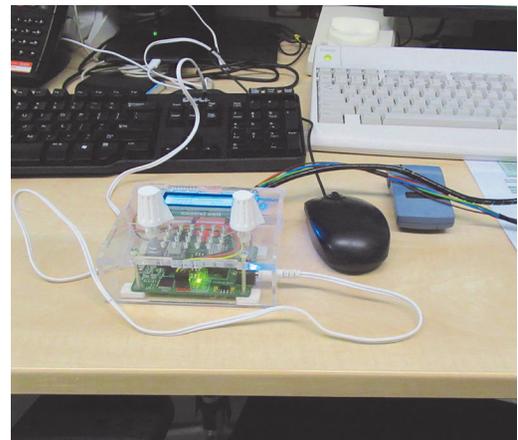


Figure 94. Control unit in the control room



In the meantime, the laboratory technician left the room. He mentioned a colleague to call when we needed anything.

The phantoms were positioned together with the prototype, the cables were rolled out, control unit worked. Finally, we were able to start the test!

Figure 95. The control room

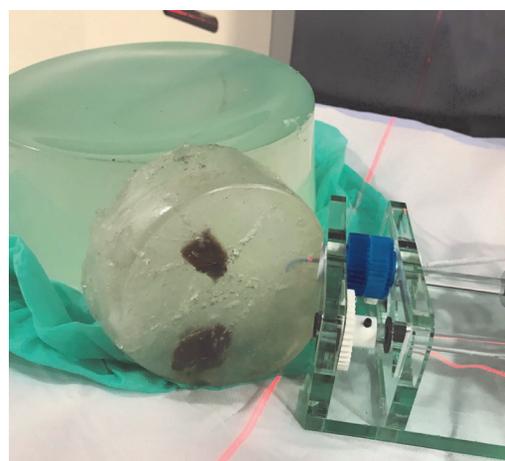
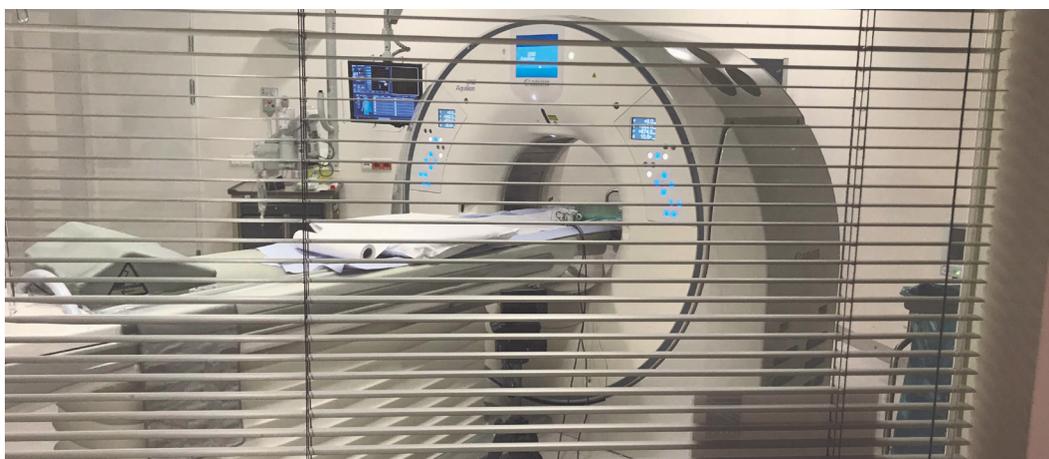


Figure 96. Setup

Dennis called the colleague to insert the right settings and some test scans were made. Despite the right setup, no needle showed up in the scans. It was hard to position the needle in the right scan plane.

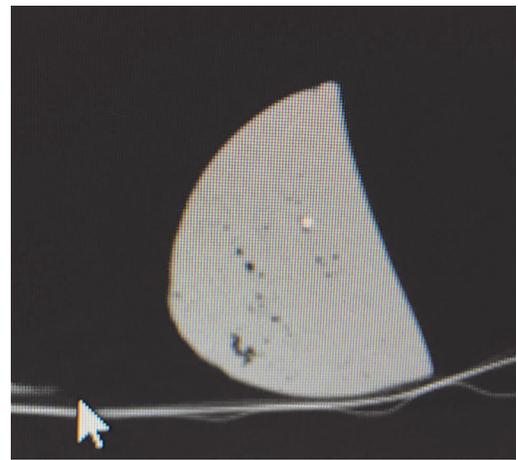
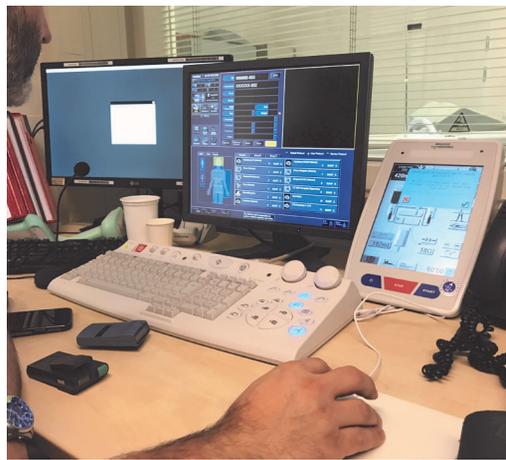
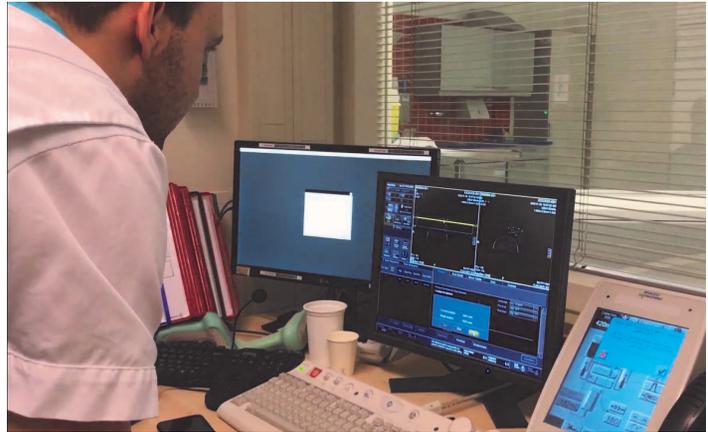


Figure 97. Adjusting the settings



To find the right position for the needle, the metal parts of the prototype needed to be in the scanned area. It caused a lot of scattering in the images, but the needle became visible!

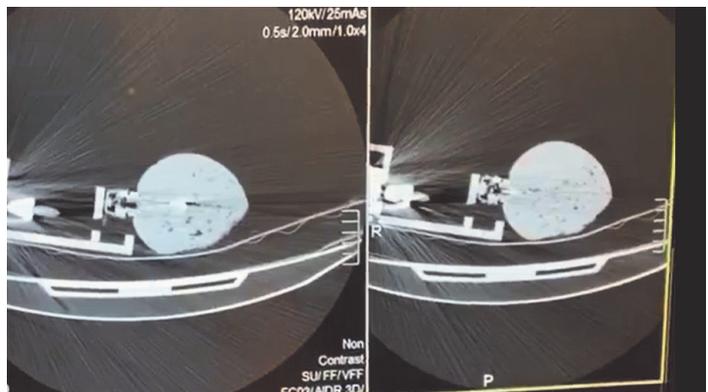
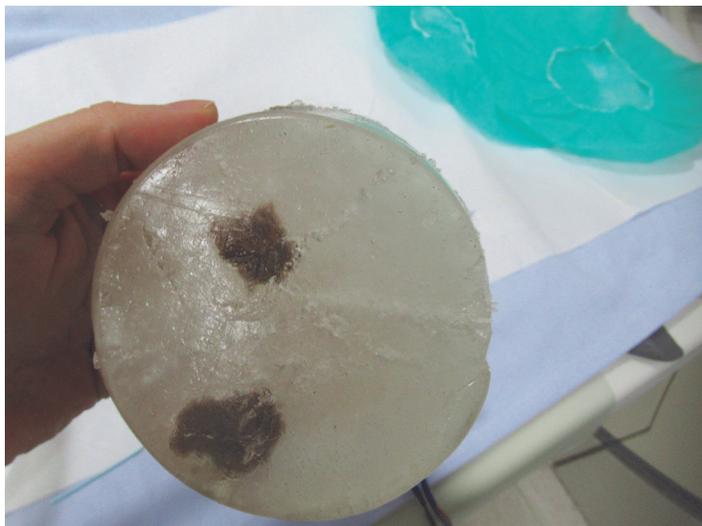


Figure 98. Scans with and without scattering



Finally, a continuous scan could be made and a video of 30 seconds was created. In the phantom, the straight lines are visible and show the tracks of the needle.

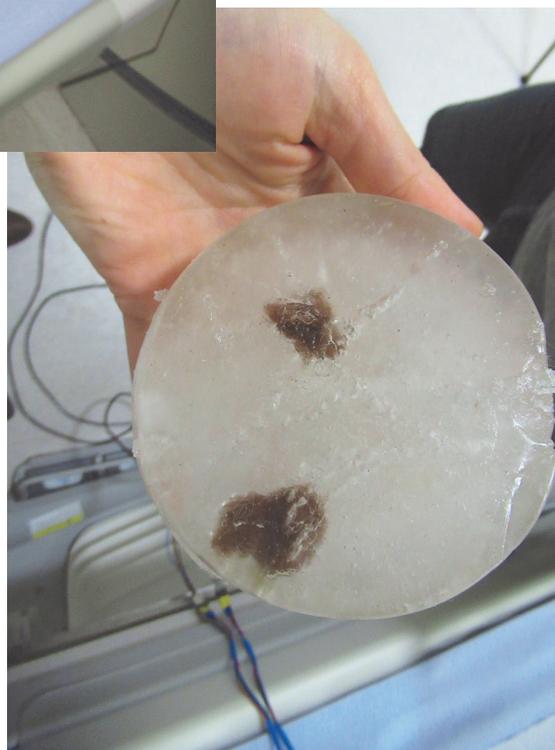


Figure 99. Paths in the phantom

# Appendix XI - Dimensions of the visual models

In figure 102, the dimensions of the visual model can be seen. In figure 100 and 101, the visual model is placed in context and shows that the motor with its current dimensions cannot be placed perpendicular to the patients body. Therefore, it needs four DOF's to reach all spots in the patient's head.

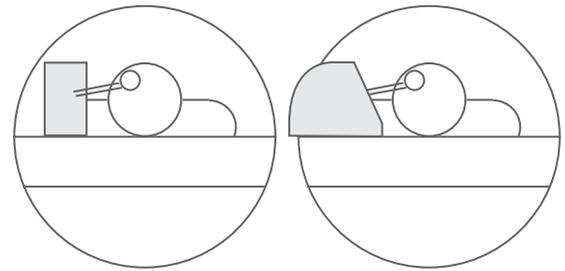


Figure 100. Parallel position

Figure 101. Perpendicular position

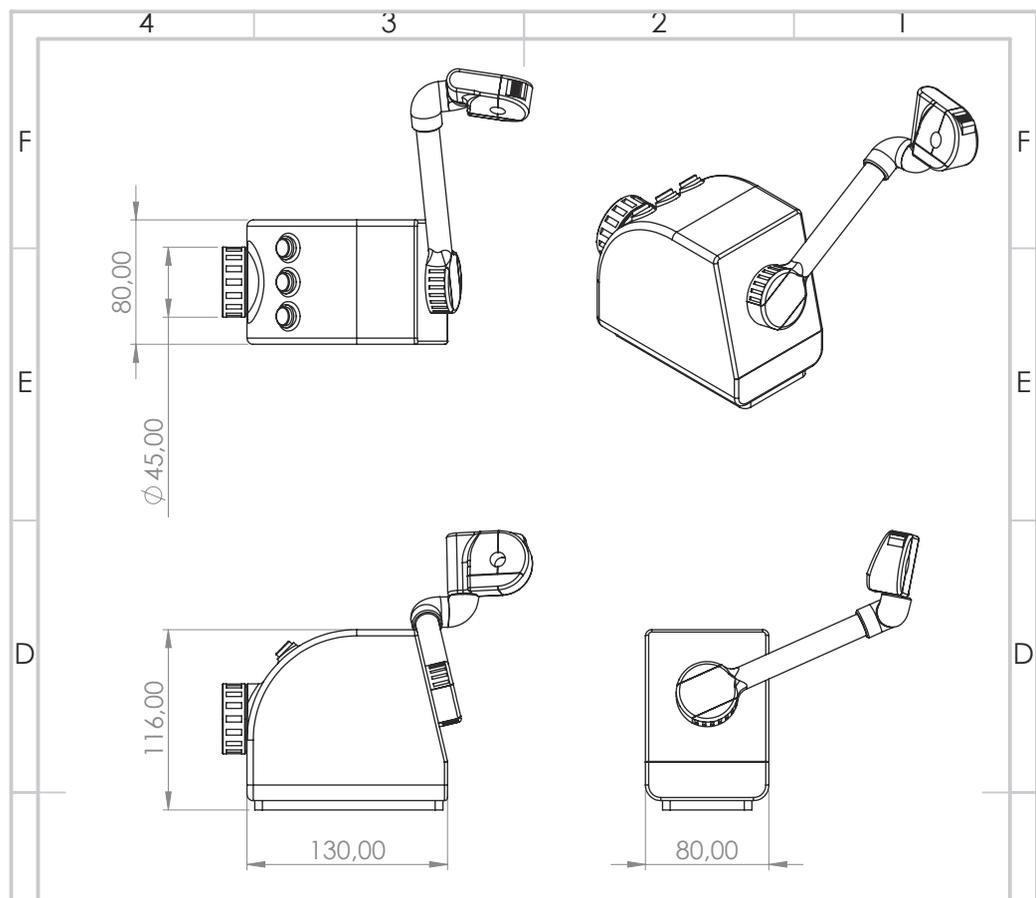


Figure 102. Dimensions

# Appendix XII - Rules and regulation

---

For determining in which class the needle control device falls, the Medical Device Classification Flowchart is used (see next page).

For the European market a CE-mark is required. To qualify for marking, 11 steps need to be undertaken.

## CE-marking

### 1. Compose a essential requirements checklist

In the document of 'Guideline medical devices', a list is stated with requirements on subjects as design, production, risk management, materials etc. Not every requirement is suited for the needle control device, so a list needs to be composed with its essential requirements.

### 2. Describe the intended use

A scope must be given, which means that the intended use must be stated but also all actions that the device should not be able to do. This part defines the tests that should be conducted. Also the intended use must be stated on the label of the device

### 3. Classify

The device should be ranked on risk for the patient and classified into one of the four classes: I, IIa, IIb and III. Next to the flowchart and the scan on the NEN website, the European party MEDDEV could be consulted for classification. For class I products, the manufacturer himself could classify the product. For all other classes, an external party needs to classify. This is done by a Notified Body. In The Netherlands, three Notified Bodies are present: DEKRA, TUV and BSI.

### 4. Quality Management

The manufacturer could start their own quality management system. It will check the quality of the production, development of the design, testing, the installations and services of the product etc. This system needs to apply to ISO 13485. If the manufacturer decides not to start a quality management system, a Notified Body should do the additional checks.

### 5. Risk Management

A crucial requirement from step one is that the device should not expose the patient and user to danger. A risk analysis should be performed and the risks should be estimated on impact. ISO 14971 explains the process.

### 6. Testing

Testing is required before a CE-mark could be given. Three aspects need to be shown: (1) the user knows how the device works and cannot make mistakes – ergonomical safety, (2) the device works as expected – clinical safety, (3) the device should not have unwanted consequences on the body of the patient (biological safety).

Multiple tests could be performed: user tests, technical tests, lab and simulation tests, etc.

**IN VITRO DIAGNOSTICS**

**NON-INVASIVE**

**INVASIVE**

**MEDICAL DEVICES**

**SPECIAL RULES**

**START**

**NON-INVASIVE**

**INVASIVE**

**ACTIVE**

**SPECIAL RULES**

<p><b>Rule 1</b> Devices intended to be used for the following purposes:</p> <ul style="list-style-type: none"> <li>- detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell transplantation;</li> <li>- detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with high or suspected high risk of propagation;</li> <li>- determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.</li> </ul>	<p><b>Rule 7</b> Devices which are controls without a quantitative or qualitative assigned value</p> <p><b>Rule 6</b> Devices, as defined by the above-mentioned classification rules</p> <p><b>Rule 5</b> The following devices, laboratory use, accessories which possess no critical characteristics, washing solutions and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic examination, if specific instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;</p> <ul style="list-style-type: none"> <li>- specimen receptacles.</li> </ul>	<p><b>Rule 4</b> Non-invasive devices which come into contact with injured skin or mucous membrane (also applies to the invasive devices that come into contact with injured mucous membrane); to be used as a mechanical barrier, for compression or for absorption of exudates;</p> <p><b>OR</b></p> <p>to be used principally for injuries to skin which have breached the dermis or mucous membrane and remain only near by secondary intent;</p> <p><b>OR</b></p> <p>Principally intended to manage the micro-environment of injured skin or mucous membrane and in other cases;</p>	<p><b>Rule 5</b> Invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device;</p> <p>if they are intended for transient use</p> <p><b>OR</b></p> <p>if they are intended for short-term use</p> <p><b>OR</b></p> <p>except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity</p> <p><b>OR</b></p> <p>if they are intended for long-term use</p> <p><b>OR</b></p> <p>except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane</p>	<p><b>Rule 8</b> Implantable devices and long-term surgically invasive (and ancillary) components such as screws, wedges, plates and instrumentals) unless</p> <ul style="list-style-type: none"> <li>- are intended to be placed in the teeth</li> <li>- are intended to undergo chemical change in the body except if the devices are intended to be used in direct contact with the heart, or the central circulatory system or the central nervous system</li> <li>- are wholly or mainly absorbed or intended to administer medicinal products</li> <li>- active implantable devices or their accessories; or</li> <li>- breast implants; or surgical - total or partial joint replacements</li> <li>- spinal disc replacement implants or are implantable devices that come into contact with the spinal column</li> </ul>	<p><b>Rule 9</b> Active therapeutic devices to administer or exchange energy unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous manner, the safety and site of application of the device</p> <p><b>OR</b></p> <p>Active devices intended to control or monitor the performance of class II devices, or intended directly to influence the performance of such devices</p> <p><b>OR</b></p> <p>Active devices intended to emit ionizing radiation for therapeutic purposes, which control or monitor such devices, or which directly influence their performance</p> <p><b>OR</b></p> <p>Active devices that are intended for controlling or influencing the performance of active implantable devices</p>	<p><b>Rule 12</b> Active devices intended to administer medicinal products, body liquids or other substances to or from the body</p> <p>unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application</p>	<p><b>Rule 11</b> Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, except if such decisions have an impact that may cause:</p> <ul style="list-style-type: none"> <li>- death or an irreversible deterioration of a person's state of health;</li> <li>- a serious deterioration of a person's state of health or a surgical intervention</li> </ul> <p><b>OR</b></p> <p>Software intended to monitor physiological processes except if it is intended for monitoring of vital parameters, where the nature of variations of those parameters is such that it could lead to a direct danger to the patient</p> <p><b>OR</b></p> <p>All other software</p>	<p><b>Rule 13</b> Devices intended as an integral part, a separately considered to be a medicinal product including a medicinal blood or human plasma and that has an action ancillary to that of the device.</p>	<p><b>Rule 2</b> Devices intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration</p> <p>except when intended to determine any of the following markers:</p> <ul style="list-style-type: none"> <li>- ABO system;</li> <li>- Rhesus system;</li> <li>- Kell system;</li> <li>- Kidd system;</li> <li>- Duffy system;</li> </ul>	<p><b>Rule 3</b> Devices if they are intended:</p> <ul style="list-style-type: none"> <li>- for detecting the presence of, or exposure to, a sexually transmitted agent</li> <li>- for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;</li> <li>- for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, or foetus or embryo being tested, or to the individual's offspring;</li> <li>- for pre-natal screening of women in order to determine towards transmissible agents;</li> <li>- for determining immune status, disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient, or for the patient's offspring;</li> </ul>	<p><b>Rule 2</b> Non-invasive devices intended for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells &amp; tissues;</p> <p><b>OR</b></p> <p>blood bags</p>	<p><b>Rule 6</b> Surgically invasive devices intended for transient use unless</p> <ul style="list-style-type: none"> <li>- are reusable surgical instruments</li> <li>- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system</li> <li>- those parts of the body with these parts of the body are intended specifically for use in direct contact with the heart or central circulatory system</li> <li>- have a biological effect or are wholly or mainly absorbed</li> </ul> <p><b>OR</b></p> <p>are intended to supply energy in the form of ionizing radiation</p> <ul style="list-style-type: none"> <li>- are intended to undergo chemical change in the body</li> <li>- are placed in the teeth</li> <li>- are intended to administer medicines</li> </ul>	<p><b>Rule 7</b> Surgically invasive devices intended for short-term use unless</p> <ul style="list-style-type: none"> <li>- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system</li> <li>- with these parts of the body</li> <li>- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system</li> <li>- have a biological effect or are wholly or mainly absorbed</li> </ul> <p><b>OR</b></p> <p>are intended to supply energy in the form of ionizing radiation</p> <ul style="list-style-type: none"> <li>- are intended to undergo chemical change in the body</li> <li>- are placed in the teeth</li> <li>- are intended to administer medicines</li> </ul>	<p><b>Rule 10</b> Active devices intended for diagnosis and monitoring if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body;</p> <p><b>OR</b></p> <p>if they are intended to image in vivo distribution of radiopharmaceuticals</p> <p>if they are intended to allow direct diagnosis or monitoring processes, unless they are specifically intended for monitoring of vital physiological parameters and those parameters is such that it could result in immediate danger to the patient's cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger</p>	<p><b>Rule 15</b> Devices used for contraception or prevention of the transmission of sexually transmitted diseases unless they are implantable or long term invasive devices</p> <p><b>OR</b></p> <p>Devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses</p> <p><b>OR</b></p> <p>Devices intended specifically to sterilising medical devices unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing</p>	<p><b>Rule 16</b> Devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses</p> <p><b>OR</b></p> <p>Devices intended specifically to sterilising medical devices unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing</p> <p>This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.</p>	<p><b>Rule 17</b> Devices specifically intended for reprocessing single-use devices generated by X-ray radiation.</p>	<p><b>Rule 18</b> Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or non-viable</p> <p>unless such devices are manufactured using tissues or cells of animal origin or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.</p>	<p><b>Rule 19</b> Devices incorporating or consisting of mammary or other tissue, or their derivatives, if they present a high or medium potential for internal exposure</p> <p><b>OR</b></p> <p>if they present a low potential for internal exposure</p> <p><b>OR</b></p> <p>if they present a negligible potential for internal exposure.</p>	<p><b>Rule 20</b> Invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions</p>	<p><b>Rule 21</b> Devices that are composed of combinations of substances that are intended to be introduced into the human body via a body orifice or are absorbed by or locally dispersed in the human body; if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;</p> <p>if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;</p> <p><b>OR</b></p> <p>if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities</p> <p><b>OR</b></p> <p>all other cases.</p>	<p><b>Rule 22</b> Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines by the device, such as closed loop systems or automated external defibrillators</p>	<p><b>Rule 23</b> Devices that are composed of combinations of substances that are intended to be introduced into the human body via a body orifice or are absorbed by or locally dispersed in the human body; if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;</p> <p>if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;</p> <p><b>OR</b></p> <p>if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities</p> <p><b>OR</b></p> <p>all other cases.</p>	<p><b>Rule 24</b> Devices specifically intended for reprocessing single-use devices generated by X-ray radiation.</p>
--	--	---	---	--	---	--	---	---	--	--	--	--	---	---	--	--	---	--	--	--	---	--	---	---

**START**

1. In case of first classification of your product, always consult the original text of MDR 2017/745 or IVDR 2017/756.  
2. Where necessary, we warmly expressed or inspired, as to the media obtained from the use of the information in the graph.  
XENDO AG - 09

## 7. Clinical evaluation and research

The clinical evaluation is based on the characteristics, performance and side effects of the device. Many times literature studies of other similar products are used for prove. If it is not convincing enough and the risk management and tests also require more clinical research, additional tests need to be conducted. Often this is required for innovative devices ranked in class IIb and III, so probably this will be the case for the needle control device. The Notified Body could be consulted for this extra studies and how deep they must go. Appendix X of the document Guideline Medical Devices states how the clinical evaluation must be performed. There are also accompanying documents like MEDDEV 2.7 and ISO 14155.

## 8. Technical documentation

The technical documentation's aim is to make the process controllable to see if the device applies to all requirements. This could be done by a Notified Body or in The Netherlands the Inspectie voor de Gezondheidszorg. The technical documentation describes the device and its design process. Furthermore, it consists of the description of the label, risk benefit analysis, clinical research and evaluation etc. This documentation needs to be saved for at least five years after the last device is produced.

## 9. Rating of the device

The Notified Body will finally give a rating to the device. Depending on the class, the rating is elaborated. So for the needle control device, it will be an extensive rating. The result will be a declaration of conformity signed by the Notified Body and the manufacturer, including the technical documentation.

## 10. Registration and including the CE-mark

The Notified Body will then register the device for the CE-mark. For class I products, the manufacturer can do that himself. The CE-mark could be included on the label and the design of the device. It has to follow strict rules on the design of the CE-mark (figure 103).

## 11. Post market surveillance

After the introduction on the market, the manufacturer is not done. He keeps responsibility to track the devices, which means keeping track of complaints or problems so they can be solved. Also, incidents must be declared to the Inspectie voor de Volksgezondheid. An incident has happened when a patients has died, or could have died, or when the health of a patient has been dramastically changed. The way of tracking the complaints, problems and incidents need to be described in a Post Market Surveillance plan. It is part of the Technical Documentation.

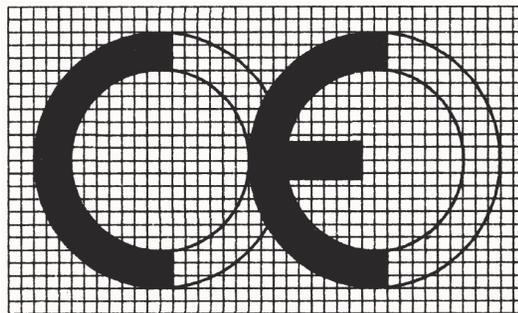


Figure 103. The CE-mark

## CE and FDA marking

These steps need to be fulfilled if the device wants a CE-mark and be sold on the European market. For selling in the US, another mark needs to be applied for: the Food and Drug Administration (FDA). No further research is done yet for this mark.



Radboudumc