EMF Evaluation Report

Date of Report	28/06/2024	**Client's Contact person:**	Pietro Zacchera
Number of pages:	26	**Responsible Test engineer:**	Kalle Orava
Testing laboratory:	**Verkotan Oy** Elektroniikkatie 17 90590 Oulu Finland	**Client:**	**Sequana Medical NV** Technoparkstrasse 1 8005 Zurich Switzerland
Tested device	**alfapump System**		
Related reports:	-		
Testing has been carried out in accordance with:	**680106 D01 RF Exposure Wireless Charging App v04** Rf exposure considerations for low power consumer wireless power transfer applications **47CFR §2.1093** Radiofrequency Radiation Exposure Evaluation: Portable Devices **Customer specified test plan**		
Documentation:	The test report must always be reproduced in full; reproduction of an excerpt only is subject to written approval of the testing laboratory		
Test Results:	**The EUT does not fulfill requirements set by the standards at the operational separation distance.** The test results relate only to devices specified in this document		
Date and signatures:	28.06.2024 *Miia Nurkkala* **Laboratory Manager**		

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1. SUMMARY OF EMF TEST REPORT

1.1 Test Details

Equipment under Test (EUT):

Product:	alfapump System
Manufacturer:	Sequana Medical NV
Serial Number:	5851
HW / SW ID:	HW version: 05.00 SW version: Dedicated FW for continuous power emission: #02529, Rev 01.00
FCC ID:	2BDJN01475
Model:	Smart Charger
DUT Number:	20973
State of the Sample:	Production sample

Testing information:

Testing performed:	14.11.2023 – 13.12.2023; 25.06.2024
Notes:	-
Document ID:	FCC_EMF_Report_alfapump System ID6620_25062024.docx
Document history/changes:	25.06.2024, Added test position 5
Measurement performed by:	Kalle Orava, Ilari Kinnunen
FCC Test Firm Designation number:	FI0005

1.2 Maximum Results

1.2.1 KDB 680106 D01

The maximum reported electric field and magnetic field strength values are shown in tables below.

1.2.1.1 E-field

Operation mode	Test position	Test	Distance to DUT* [mm]	Frequency [kHz]	MPE Limit [V/m]	Measured value [V/m]
Charging	3	E-field strength	0	296	614	212
Charging	3	E-field strength	30	296	614	54.3
Charging	1	E-field strength	100	296	614	9.46
Charging	2	E-field strength	200	296	614	1.83

1.2.1.2 H-field

Operation mode	Test position	Test	Distance to DUT* [mm]	Frequency [kHz]	MPE Limit [A/m]	Measured value [A/m]
Charging	3	H-field strength	0	296	1.63	269
Charging	5	H-field strength	30	296	1.63	87.1
Charging	5	H-field strength	100	296	1.63	8.63
Charging	4	H-field strength	200	296	1.63	1.31

1.2.2 Simultaneous transmission Analysis

Simultaneous transmission analysis of ISM and WPT transmitters is done by calculation of total exposure ratio i.e., TER. If TER<1 the product conforms to the requirements of the standards.

1.2.2.1 E-field

Simultaneous Sources	Summed Components	Distance to DUT [mm]	TER
WPT + ISM	E-field strength + SAR	0	0.16
WPT + ISM	E-field strength + SAR	30	0.05
WPT + ISM	E-field strength + SAR	100	0.04
WPT + ISM	E-field strength + SAR	200	0.04

1.2.2.2 H-field

Simultaneous Sources	Summed Components	Distance to DUT [mm]	TER
WPT + ISM	H-field strength + SAR	0	27235.16
WPT + ISM	H-field strength + SAR	30	2855.40
WPT + ISM	H-field strength + SAR	100	28.07
WPT + ISM	H-field strength + SAR	200	0.68

2. DESCRIPTION OF THE DEVICE UNDER TEST (DUT)

The DUT is a wireless charging system for medical implant, which supports ISM 915 MHz, 296 kHz WPT, GSM, WCDMA and LTE. Cellular technology is only used when the DUT is docked to a charger, and not being used for charging. The device operates at a distance of 0 – 30mm from patient.

The DUT was tested in power mode, which is considered worse than normal operation according to customer. In continuous mode test, power stage voltage is fixed by a dedicated firmware used for these tests and its value is 5.3V. This value represents a nominal charging voltage value in which the recharging process provided by the Smart Charger is always active (considered a worst-case scenario).

Figure 1. Docking station and alfapump

Device Category	Portable
Exposure Environment	Uncontrolled

2.1 Technical data of the DUT

WPT:

Operating Frequency [kHz]	Antenna Type	Maximum Nominal Power [W]
296	Magnetic loop	<15W

ISM:

Bands	Transmitter Frequency Range [MHz]
ISM	907

2.2 Text Exclusions

FCC SAR test exclusion threshold is calculated according to 447498D04 Interim General RF Exposure Guidance, equation B.2 and B.1:

$$Pth\ (mW) = \begin{cases} ERP_{20\ cm}\ (d\ /\ 20cm)^{x} & d \le 20cm \\ ERP_{20\ cm} & 20cm < d \le 40cm \end{cases} \quad \text{(Equation 1)}$$

where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\ cm}\sqrt{f}}\right) \quad \text{(Equation 2)}$$

and frequency f is in GHz, d is the separation distance (cm), and ERP20cm is per Equation (B.1) below.

$$ERP20cm\ (mW) = \begin{cases} 2040f & 0.3 \le f < 1.5GHz \\ 3060 & 1.5GHz \le f \le 6GHz \end{cases} \quad \text{(Equation 3)}$$

Transmission mode	Frequency [GHz]	Separation distance [cm]	P_{th} [mW]
ISM	907	0.5	8.23

2.2.1.1 Maximum defined Output Power and ERP

According to *"28950_01.00_Smart Charger radio frequency test report according to FCC Part 15.249 and RSS210.pdf"*, maximum field strength of the smart charger is 0.0642 V/m.

EIRP was calculated from field strength values using following formula, according to *"412172 Determining ERP and ERIP DR01"*:

$$EIRP = (FS * D)^2 / 30 \qquad \text{(Equation 4)}$$

where,
G is the numerical gain of the transmit antenna, referenced to isotropic gain, in dBi
FS is the measured electric field strength in Volts/metre
TP is transmitter output power delivered to the antenna in Watts
D is the distance in metres between the measurement antenna and the transmit antenna (of the EUT)
EIRP = $(0.0642 * 3)^2 / 30$
EIRP = 0.0012 W = 1.23 mW

According to Appendix A at 447498D04 Interim General RF Exposure Guidance, the equation (B.2.) defines the thresholds for available maximum time-averaged power or maximum time-averaged ERP, whichever is greater. Since the maximum output power is greater than the ERP, it is used for SAR test exclusion.

Transmission mode	**Output power [dBm]**	**Output power [mW]**	**Power Gain of Antenna, G [dBi]**	**ERP Output power [dBm]**	**ERP Output power [mW]**	**P_{th} [mW]**
ISM	0	1	N/A	-1.25	0.75	8.23

The maximum output power for ISM transmitter is below the test exclusion threshold.

2.3 Simultaneous transmission

Calculated ISM SAR:

For simultaneous transmission evaluation the estimated standalone SAR values are calculated according to the following equation below.

$$SAR_{estimated} = 0.4 * Pant/Pth\ [w/kg] \quad \text{(Equation 4)}$$

Estimated ISM 13.56 MHz SAR = 0.4*(1.23/8.23) = 0.06 W/kg

3. TEST EQUIPMENT

Test Equipment	Model	Serial Number	Calibration Date
E- and H-field meter	MAGPy-8H3D-E3D	3037	31.08.2023
Data Acquisition System	MAGPy-DAS	3060	31.08.2023

3.1 Test setup

3.1.1 KDB 680106 D01

Four measurement distances were used during WPT testing. The distance is measured from the radome of the probe to the edge of the device. Testing was done on a wooden table with a plastic cover, free of metal objects. Peak E- and H-field was measured using max hold functionality, from the rear of the DUT, using 5 different positions.

Figure 2. Naming convention of the measurement positions.

Photos of the test setup are shown in Appendix A.

3.2 Limits

Limits for MPE specified in KDB 680106 D01 (47 CFR § 1.1310, Table 1). The operating frequency for the charger is 296 kHz.

Thus, limits of 614 V/m were used for E-field and 1.63 A/m for H-field.

TABLE 1 - LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ^{2})	Averaging time (minutes)
(A) Limits for Occupational/Controlled Exposure				
0.3-3.0	614	1.63	* 100	6
3.0-30	1842/f	4.89/f	* 900/f ^{2}	6
30-300	61.4	0.163	1.0	6
300-1,500			f/300	6
1,500-100,000			5	6
(B) Limits for General Population/Uncontrolled Exposure				
0.3-1.34	614	1.63	* 100	30
1.34-30	824/f	2.19/f	* 180/f ^{2}	30
30-300	27.5	0.073	0.2	30
300-1,500			f/1500	30
1,500-100,000			1.0	30

Figure 3. MPE Limits

4. MEASUREMENT UNCERTAINTY

Uncertainty component	Tolerance [dB]	Distr.	Div.	ci	Std. unc. [dB]
Amplitude calibration	0.44	N	1	1	0.44
Probe anisotropy	0.01	R	1.732	1	0.01
Probe dynamic linearity	0.10	R	1.732	1	0.06
Probe freq domain response	0.25	R	1.732	1	0.14
Detection limit	0.09	R	1.732	1	0.05
Read electronics	0.00	N	1	1	0.00
Repeatability	0.10	N	1	1	0.10
Vertical positioning	0.15	N	1	1	0.15
Horizontal positioning	0.13	N	1	1	0.13
Probe orientation	0.03	N	1	1	0.03
Sensor displacement	0.10	R	1.732	1	0.06
Source current	0.16	N	1	1	0.16
Physical source tolerance	0.50	R	1.732	1	0.29
Numerical uncertainty	0.30	R	1.732	1	0.17
Combined uncertainty [dB]					0.64
Extended uncertainty ($k = 2$) [dB]					1.3

Table 8.2: Preliminary uncertainty budget for H_{tot} measured in the verification tests

Uncertainty component	Tolerance [dB]	Distr.	Div.	ci	Std. unc. [dB]
Relative amplitude calibration	0.20	N	1	1	0.20
Probe anisotropy	0.01	R	1.73	1	0.01
Probe dynamic linearity	0.10	R	1.73	1	0.06
Probe freq domain response	0.00	R	1.73	1	0.00
Detection limit	0.00	R	1.732	1	0.00
Read electronics	0.00	N	1	1	0.00
Repeatability	0.10	N	1	1	0.10
Vertical positioning	0.17	N	1	1	0.17
Horizontal positioning	0.07	N	1	1	0.07
Sensor displacement	0.13	R	1.73	1	0.08
Source current	0.00	N	1	1	0.00
Physical source tolarance	0.50	R	1.73	1	0.29
Numerical uncertainty	0.30	R	1.73	1	0.17
Combined uncertainty [dB]					0.45
Extended uncertainty ($k = 2$) [dB]					0.9

Table 8.3: Preliminary uncertainty budget for G_z measured in the verification tests

Uncertainty component	Tolerance [dB]	Distr.	Div.	ci	Std. unc. [dB]
H_{tot} uncertainty	0.64	N	1	1	0.64
G_z uncertainty	0.45	N	1	1	0.45
Combined uncertainty [dB]					0.79
Extended uncertainty ($k = 2$) [dB]					1.6

Table 8.4: Preliminary uncertainty budget for SAR 10 g and E_{cube} measured in the verification tests

Figure 4. MAGPy Uncertainty

5. TEST RESULTS

Test description	Findings
A frequency span from 3 kHz to 10 MHz was scanned to check for spurious.	With the wireless charger, spurious E-field/H-field above -20 dBc were not identified.
Occupied Bandwidth check.	OBW was measured and found to be less than 6 kHz.
Four positions of the DUT were measured from the rear side.	(Appendix A: Photos of DUT)
E- and H-field measurement was performed with increased monitoring period.	Results in the table below.

5.1 Electric Field Results

Measurement direction	Test position	Separation distance [mm]	E-Field [V/m]	E-Field Limit [V/m]
Rear	1	0	149	614
Rear	2	0	171	
Rear	3	0	212	
Rear	4	0	119	
Rear	5	0	33.9	
Rear	1	30	47.6	
Rear	2	30	38.8	
Rear	3	30	54.3	
Rear	4	30	41.8	
Rear	5	30	40.8	
Rear	1	100	9.46	
Rear	2	100	8.79	
Rear	3	100	8.5	
Rear	4	100	7.53	
Rear	5	100	9.42	
Rear	1	200	1.81	
Rear	2	200	1.83	
Rear	3	200	1.55	
Rear	4	200	1.67	
Rear	5	200	1.62	

5.2 Magnetic Field Results

Measurement direction	Test position	Separation distance [mm]	H-Field [A/m]	H-Field Limit [A/m]
Rear	1	0	264	1.63
Rear	2	0	263	
Rear	3	0	269	
Rear	4	0	264	
Rear	5	0	253	
Rear	1	30	66.3	
Rear	2	30	64	
Rear	3	30	66.1	
Rear	4	30	70.5	
Rear	5	30	87.1	
Rear	1	100	7.54	
Rear	2	100	7.1	
Rear	3	100	7.56	
Rear	4	100	8.12	
Rear	5	100	8.63	
Rear	**1**	**200**	**1.2**	
Rear	**2**	**200**	**1.21**	
Rear	**3**	**200**	**1.23**	
Rear	**4**	**200**	**1.31**	
Rear	**5**	**200**	**1.29**	

6. SIMULTANEOUS TRANSMISSION ANALYSIS

WPT and ISM Simultaneous Transmission Analysis is evaluated using the following formula at 0, 3, 10 and 20 cm separation distances, for the configuration which resulted in highest E or H field:

$$TER = \sum_{k=1}^{N_S} \left(\frac{SAR_k}{SAR_{\lim}} \right) + \sum_{k=1}^{N_f} \left(\frac{MPE_{field,\,k}}{MPE_{field,\,\lim}} \right)^2 + \sum_{k=1}^{N_{PD}} \left(\frac{MPE_{PD,\,k}}{MPE_{PD,\,\lim}} \right)$$

Figure 5. FCC presentation "Mobile and Portable Device RF Exposure Policies KDB 447498"

6.1 E-field

Simultaneous Sources	Summed Components	Distance to DUT [mm]	Estimated ISM SAR [W/kg]	SAR Limit [W/kg]	Measured E-field [V/m]	E-field limit [V/m]	TER
WPT + ISM	E-field + SAR	0	0.06	1.6	212	614	0.16
WPT + ISM	E-field + SAR	30	0.06	1.6	54.3	614	0.05
WPT + ISM	E-field + SAR	100	0.06	1.6	9.46	614	0.04
WPT + ISM	E-field + SAR	200	0.06	1.6	1.83	614	0.04

6.2 H-field

Simultaneous Sources	Summed Components	Distance to DUT [mm]	Estimated ISM SAR [W/kg]	SAR Limit [W/kg]	Measured H-field [A/m]	H-field limit [A/m]	TER
WPT + ISM	H-field + SAR	0	0.06	1.6	269	1.63	27235.16
WPT + ISM	H-field + SAR	30	0.06	1.6	87.1	1.63	2855.40
WPT + ISM	H-field + SAR	100	0.06	1.6	8.63	1.63	28.07
WPT + ISM	H-field + SAR	200	0.06	1.6	1.31	1.63	0.68

APPENDIX A: PHOTOS OF THE DUT

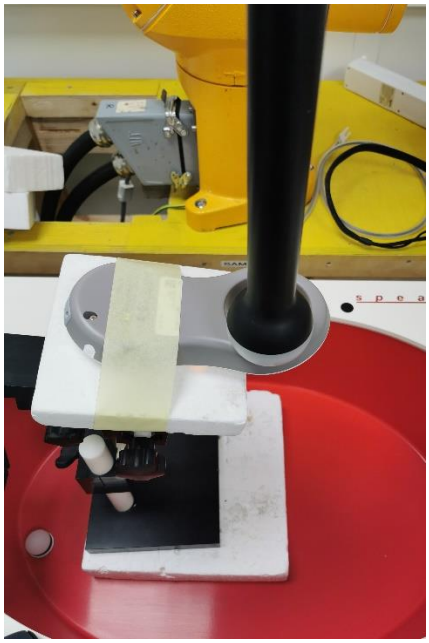

Figure 6. Test position 1, separation distance 0mm

Figure 7. Test position 2, separation distance 0mm

Figure 8. Test position 3, separation distance 0mm

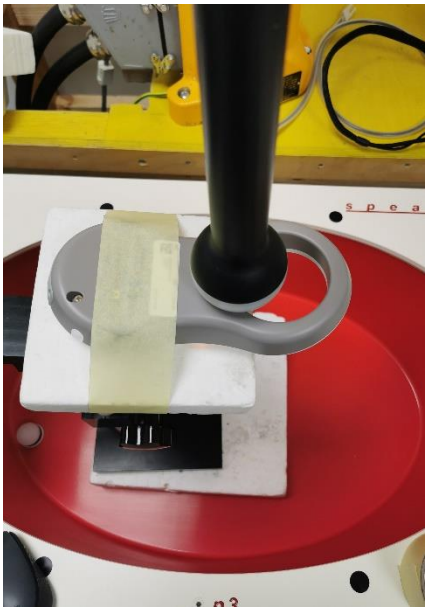

Figure 9. Test position 4, separation distance 0mm

Figure 10. Test position 5, distance 0mm

Figure 11. Test position 1, separation distance 30mm

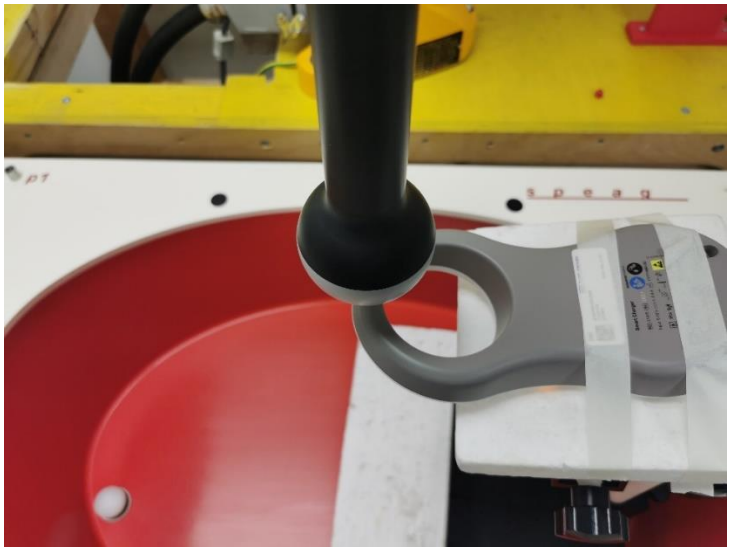

Figure 12. Test position 2, separation distance 30mm

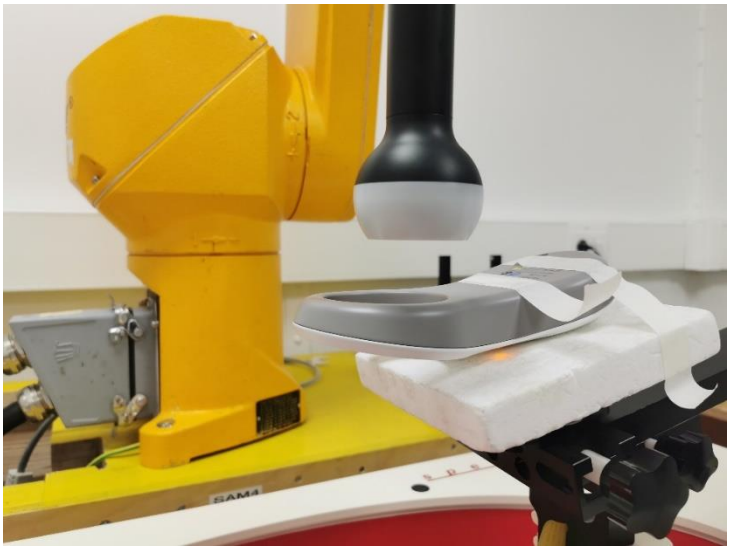

Figure 13. Test position 3, separation distance 30mm

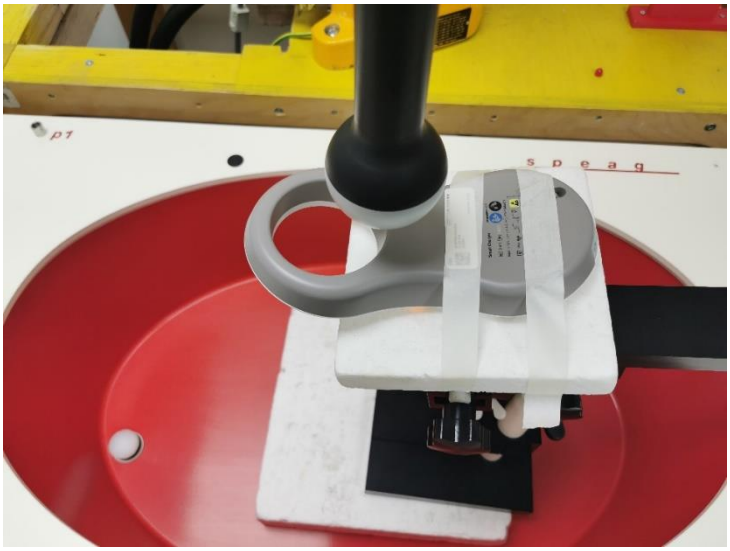

Figure 14. Test position 4, separation distance 30mm

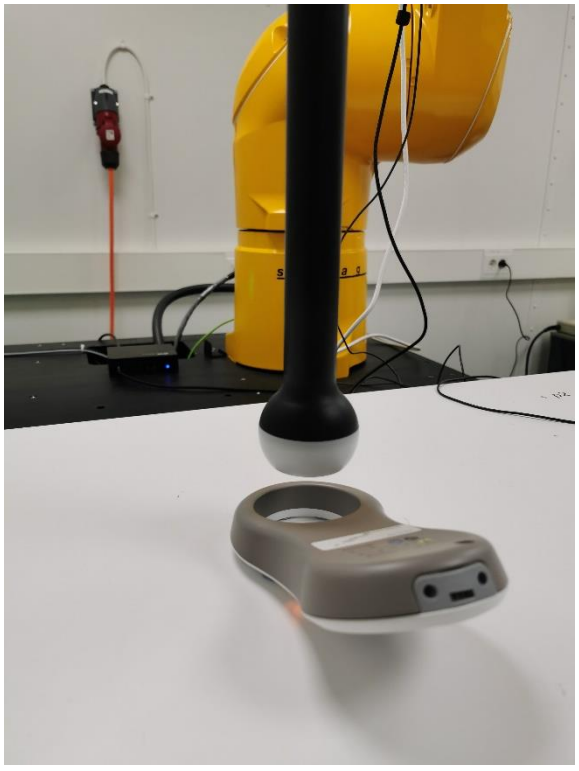

Figure 15. Test position 5, separation distance 30mm

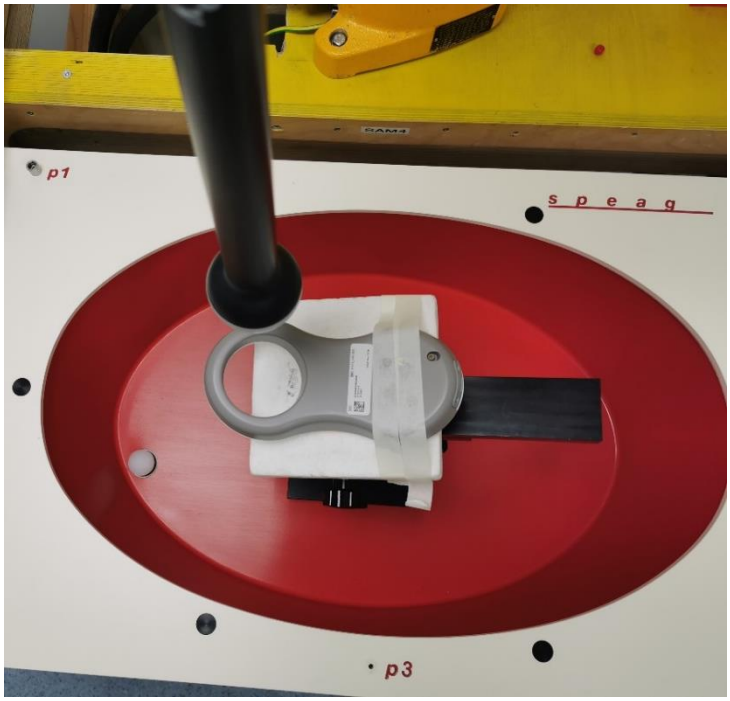

Figure 16. Test position 1, separation distance 100mm

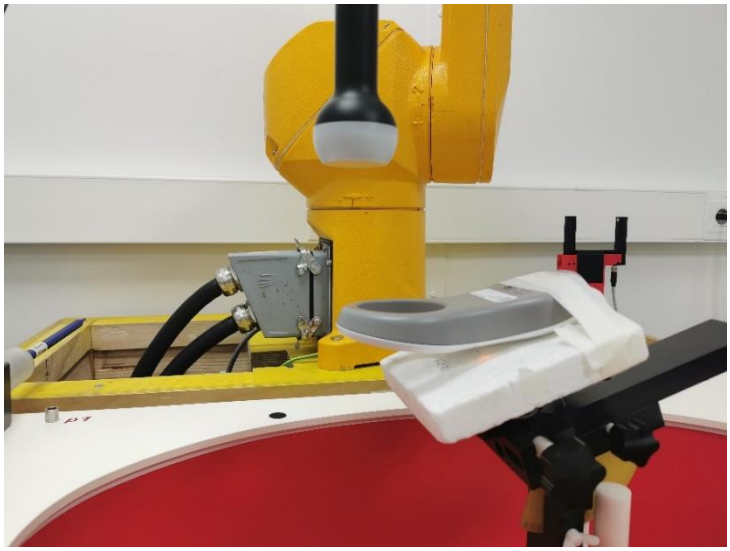

Figure 17. Test position 2, separation distance 100mm

Figure 18. Test position 3, separation distance 100mm

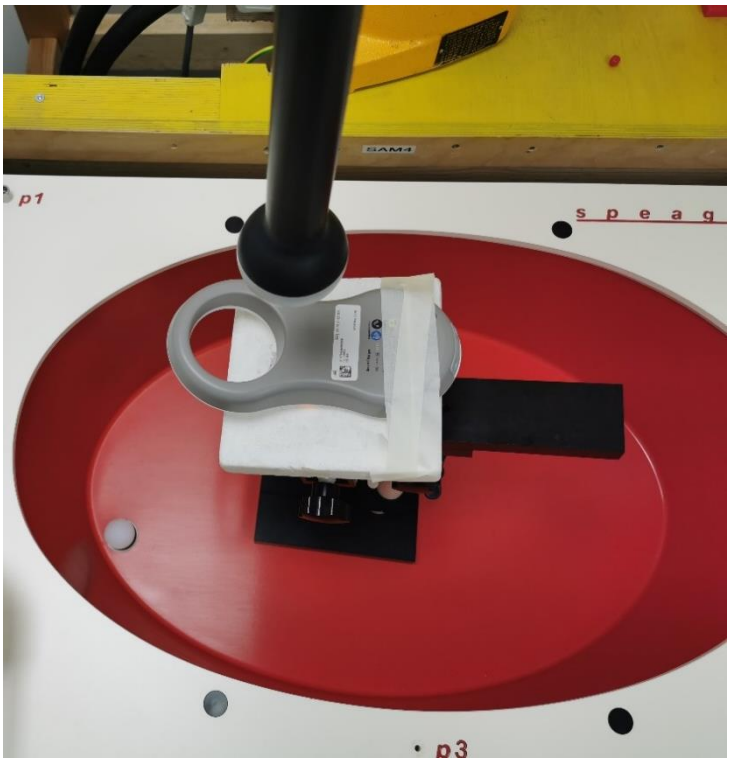

Figure 19. Test position 4, separation distance 100mm

Figure 20. Test position 5, separation distance 100mm

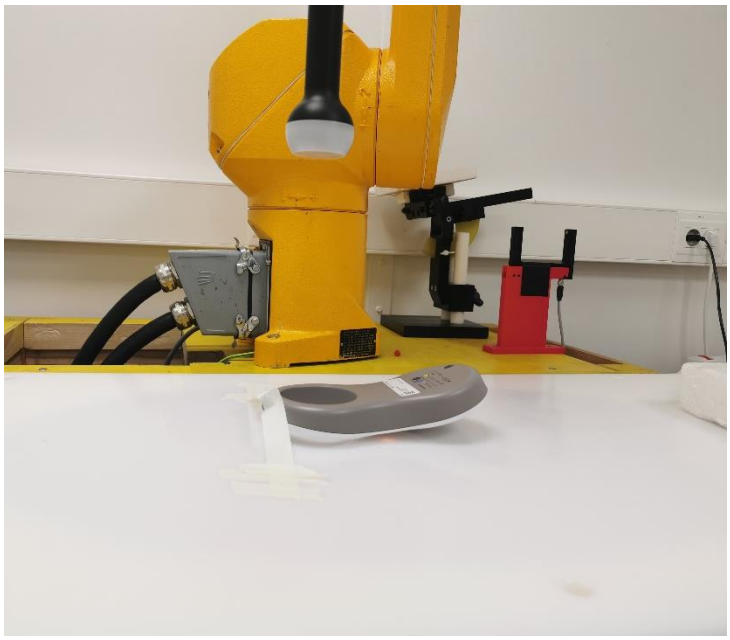

Figure 21. Test position 1, separation distance 200mm

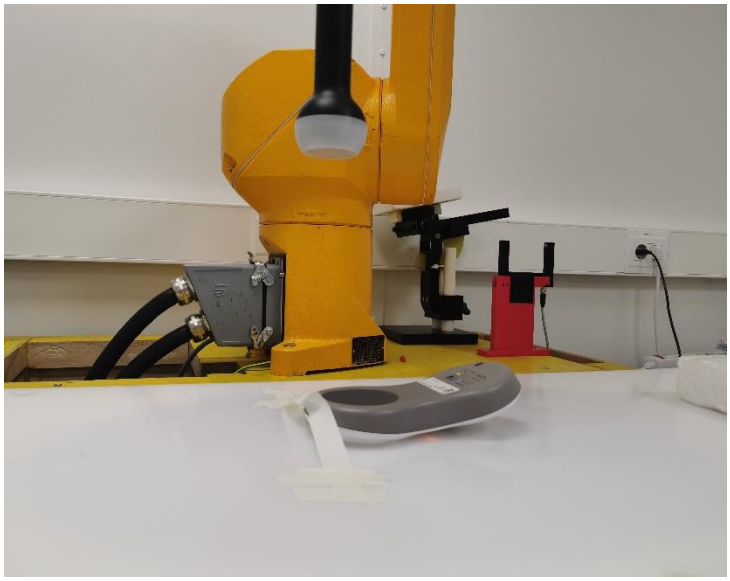

Figure 22. Test position 2, separation distance 200mm

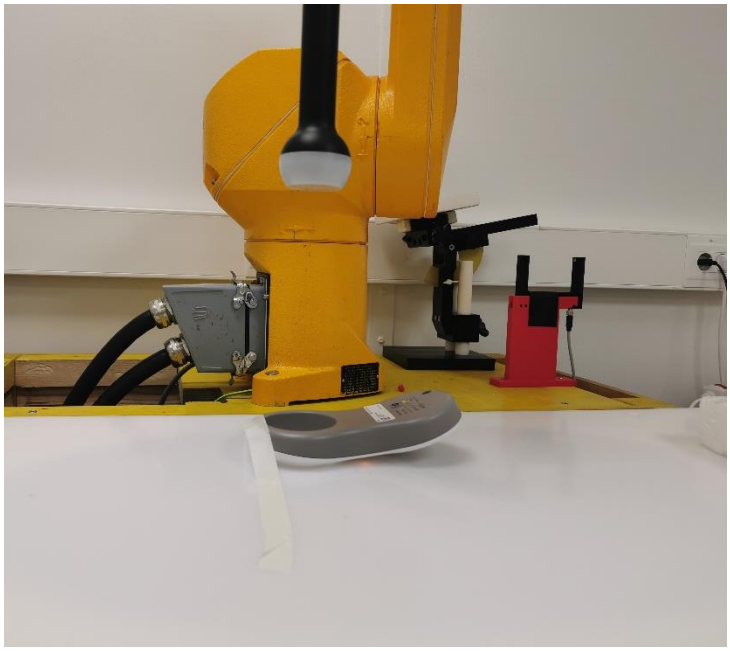

Figure 23. Test position 3, separation distance 200mm

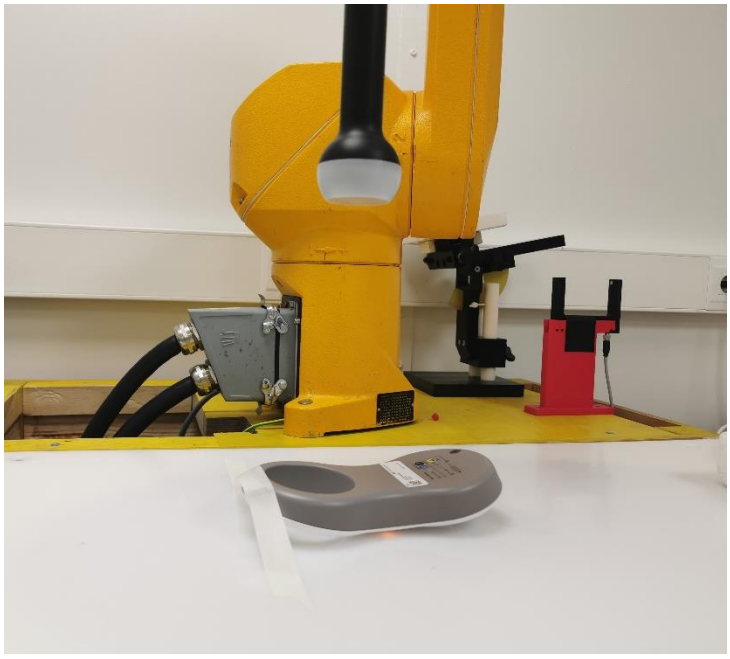

Figure 24. Test position 4, separation distance 200mm

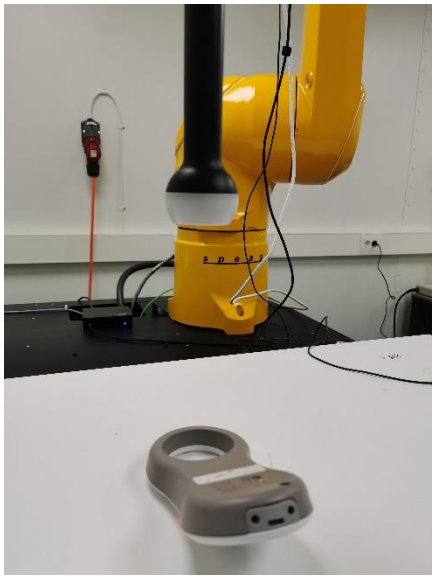

Figure 25. Test position 5, separation distance 200mm