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1 PURPOSE

This document shows the evaluation of compliance with given limits for human exposure.

2 SCOPE

In scope of the test is the NFC Unit on Sensor Frontend PCB (F00044). F00044 is part of e.g. the NICCI Hand Module (PC6510).

3 REFERENCES

Ref	Doc id	Document name
[1]	N/A Website reference	Legal Information Institute. (2020, August 24). *47 CFR § 2.1093 - Radiofrequency radiation exposure evaluation: portable devices.* [ONLINE]. Available: https://www.law.cornell.edu/cfr/text/47/2.1093
[2]	N/A Official document reference	IEEE Std. C95.1, 1999 Edition EEE Standard for Safety Levels with Respect to Human Exposure to Electric, Magnetic, and Electromagnetic Fields, 0 Hz to 300 GHz
[3]	N/A Official document reference	447498 D01 General RF Exposure Guidance v06 October 23, 2015
[4]	REP-000782 - 01	N4420013 - NFC Module - Report
[5]	N/A Official document reference	Numerical Assessment of Specific Absorption Rate in the Human Body Caused by NFC Devices 03 June 2010

4 DEFINITIONS

Definition	Explanation
NFC	Near Field Communication
PCB	Princted Circuit Board
NICCI	Name of Pulsion's Medical Device
RF	Radio Frequency
SAR	Specific Absorption Rate

5 DESCRIPTION OF DEVICE

5.1 General product information

No	Description
1	PulsioFlex Monitor (PC4000/ 6882747)
2	NICCI Module (PC6500/6889361)
3	NICCI Mouse (PC6510 /6889371)

No	Description
4	NICCI Sensor S/M/L - S (PV6550/ 6889384) - M (PV6551/ 6889385) - L (PV6552/ 6889386)
5	NICCI Upper Arm Cuff, S/M/L/XL - S (PC6531/ 6889375) - M (PC6532/ 6889376) - L (PC6533/ 6889377) - XL (PC6534/ 6889378)

Figure 1: General product information of NICCI

The NICCI Module (2) is an accessory of PulsioFlex (1) monitor.
To the NICCI Module, the NICCI Mouse (3) is connected. Depending on the size of the patient, a specific NICCI sensor ((4), size S, M, or L) is clipped on the NICCI Mouse. The NICCI Upper Arm Cuff (5) serves as reference measuring tool for the system.
A patient applies its finger to the NICCI Sensor. In this way, its blood pressure can be measured.
The NFC module, which is item of interest for this document, is integrated into NICCI Mouse for bringing it into operation.

5.2 Operational Description of RF components

The NICCI NFC Unit is used to detect the NFC Tag in NICCI Sensor, when attached to NICCI Mouse. When attached, it exchanges data via wireless connection. The microcontroller receives the information from NFC reader chip if the NFC tag is present or not and forwards this information to a host module (e.g. NICCI Module) via serial interface. The NFC reader chip is situated on the Sensor Fronted PCBA F000044, together with the integral antenna and its crystal oscillator with 27.12 MHz. The NFC reader chip works with an operating frequency of 13.56 MHz to communicate with the NFC tag. When the sensor is clipped on the mouse, there is a distance of 8.6 mm between the antenna and the NFC Tag.
The communication between NFC reader chip and microcontroller 2nd µC is through I2C serial interface using a frequency of 400 kHz. For communication the protocol according to ISO 15693 is used. The microcontroller 2nd µC is responsible for the communication with the NFC reader chip and uses a clock frequency of 12 MHz. The microcontroller 2nd µC is situated on the Controller PCBA F000043, together with another microcontroller DSP, which uses a clock frequency of 20 MHz. The microcontroller DSP is responsible for the communication with the host module.

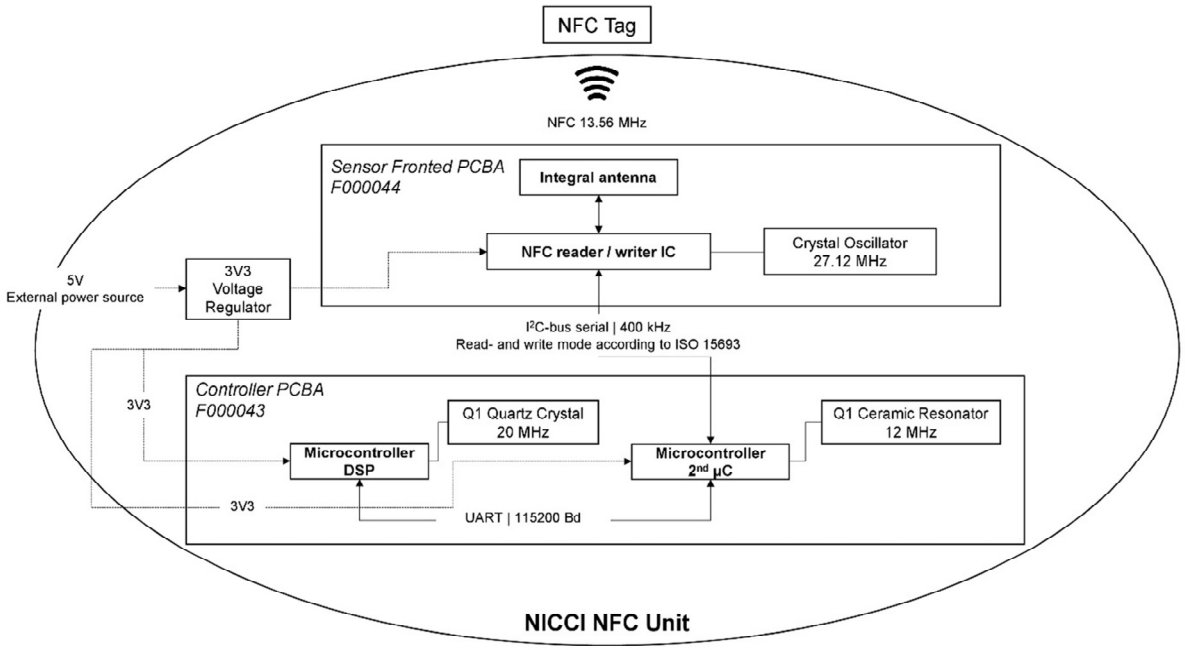

Figure 2: Block diagram of NICCI NFC Unit with NFC Tag

5.3 NFC Components

Table 1 shows the exact NFC components:

Table 1: Key components of RF module

Test item component	Type
NFC reader chip	NXP CLRC663
NFC reader antenna	Integrated antenna design, quadratic with 2.5cm side length and four turns
NFC Tag	NXP SL2S6002 ICODE DNA

The RF Module communicates with the following tag, which defines the communication standard type for the NCF reader. Therefore, the NFC tag serves as test equipment:

Table 2: NFC tag

Communication contra part	Type
NFC tag chip	ICODE DNA
Communication standard used	ISO15693

6 APPLICABLE STANDARDS

- FCC 47 CFR § 2.1093: Radiofrequency radiation exposure evaluation: portable devices.
- IEEE Std C.95.1 :2005

7 EVALUATION METHODS

In order to evaluate the compliance of NFC module with FCC standard, the following procedure is performed:

- An introduction into the requirements of the applicable standard is given
- The radiated power of used NFC reader (chip and antenna) has been exemplary calculated. The calculative evaluation has been done in alignment with an support engineer from NXP
- Additional research has been done about specific absorption rate in the human body caused by NFC Devices

8 CONSIDERATION

8.1 Introduction to standards

8.1.1 Introduction to FCC 47 CFR § 2.1093

According to [1], (d), "The limits to be used for evaluation are based generally on criteria published by (…) ANSI/IEEE C95.1-1992" [2].
When the specific absorption rate (SAR) is taken as maximum permissible value, a conservative minimum value P_{max} can be derived from, which is the SAR maximum value (SAR_{max}) multiplied by tissue volume *(m):*

$$P_{max} = SAR_{max} \times m$$

So according to [2], chapter 4.2, the following can be calculated:

Table 3: Calculation of conservative minimum value of hands

SAR_{max} W/kg	*m* g	P_{max} mW	Exposition	Area of the body
4	10	40	Uncontrolled environment	hands, wrists, feet, ankles
20	10	200	Controlled environment	hands, wrists, feet, ankles

As result, the given acceptance criteria for use with CNAP System is that the RF Module must have P_{max} of 40mW.

8.1.2 Introduction to FCC General RF Exposure Guidance

According to [3], chapter 4.2.3 do "Devices that are designed or intended for use on extremities, or mainly operated in extremity only exposure conditions, i.e., hands, wrists, feet and ankles, may require extremity SAR evaluation. When the device also operates in close proximity to the user's body, SAR compliance for the body is also required. The 1-g body and 10-g extremity SAR Test Exclusion Thresholds in 4.3 should be applied to determine SAR test requirements."
When applying *this SAR Test Exclusion Thresholds in 4.3*, Appendix C of [3] becomes applicable.

Appendix C

***SAR Test Exclusion Thresholds* for < 100 MHz and < 200 mm**

Approximate SAR test exclusion power thresholds at selected frequencies and test separation distances are illustrated in the following table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	< 50	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	mm
100	237	474	481	487	494	501	507	514	521	527	534	541	547	554	561	567	
50	308	617	625	634	643	651	660	669	677	686	695	703	712	721	729	738	
10	474	948	961	975	988	1001	1015	1028	1041	1055	1068	1081	1095	1108	1121	1135	
1	711	1422	1442	1462	1482	1502	1522	1542	1562	1582	1602	1622	1642	1662	1682	1702	mW
0.1	948	1896	1923	1949	1976	2003	2029	2056	2083	2109	2136	2163	2189	2216	2243	2269	
0.05	1019	2039	2067	2096	2125	2153	2182	2211	2239	2268	2297	2325	2354	2383	2411	2440	
0.01	1185	2370	2403	2437	2470	2503	2537	2570	2603	2637	2670	2703	2737	2770	2803	2837	

Figure 3: Appendix C of [3]

As result and according to Figure 3 the SAR test exclusion threshold is
P_{max} < 308 mW for an operating frequency at 13.56 MHz and a reading distance of 8.6mm.

8.2 Consideration of radiated power

8.2.1 NFC components

As transmitter, the NXP CLRC663 is used. As NFC Tag, the NXP SL2S6002 ICODE DNA is implemented in opposite part, e.g. in the NICCI Sensor.

The transmitter is working with 3.3 V at max. current of 0.2 mA, which corresponds a power of 66 mW. The NFC Tag has a minimum input power of *40 µW*, including losses in the resonant capacitor and rectifier.

The rated output power of the transmitter is at 23 dBm, which corresponds to 199.53 mW, calculated acc. to the following formula:

$$P(W) = 10^{\frac{P_{dBm} - 30}{10}}$$

8.2.2 Test report

In [4], the NFC Module was tested according to the test same levels as required in [2], chapter 4.2.

Table 4: Results of testing acc. to [2], chapter 4.2

SAR_{max} W/kg	*m* g	P_{max} mW	Exposition	Area of the body	P_{meas} mW
4	10	40	Uncontrolled environment	hands, wrists, feet, ankles	7.49 e-11 8.38 e-12
20	10	200	Controlled environment	hands, wrists, feet, ankles	7.49 e-11 8.38 e-12

The results show that the P_{meas} is far under the critical value.

8.3 Additional research

In “Second International Workshop on Near Field Communication, 2010” [5] a numerical Assessment of Specific Absorption Rate in the Human Body Caused by NFC Devices has been published.

The abstract states the following:
The Near field communication technology (NFC) is applied for transferring data over short distances by maintaining an inductive coupling of the transmitter and the receiver at 13.56 MHz. The relatively high magnetic field strength in the immediate surrounding of NFC devices give rise to the question about the local personal exposure of the user holding such a device in the hand or close to the body. In the present paper personal exposure in terms of the maximum 10g-averaged specific absorption rate (SAR) while using NFC was estimated for different scenarios using MRI-based anatomically correct body models. The simulations were performed with the method of Finite Differences in Time Domain (FDTD). The numerical models of the considered NFC devices were validated by SAR measurements using a simplified homogeneous body phantom and acceptable agreement between measurements and simulations was achieved. Several exposure scenarios with a cell phone comprising NFC functionality and a stationary NFC reader were investigated considering two different body models (male 34 years, male 14 years). The results showed maximum 10g-averaged SAR-values more than two orders of magnitude below the basic restriction recommended by the International Commission for Non Ionizing Radiation Protection (ICNIRP). The absolute maximum value of the maximum 10g-averaged SAR found in the considered scenarios was 11.18 mW/kg. Therefore, it can be concluded that personal exposure due to NFC devices typically cause SAR levels far below the basic restrictions of safety guidelines.

9 CONCLUSION

The FCC 47 CFR § 2.1093 rule with its referred standards requires some considerations with respect to the exposure for humans. Especially the standards state when no extra tests become necessary. After working out of the specific requirements, considerations from different perspectives were given. The considerations showed that the NICCI NFC Unit is under the critical value, from which testing becomes necessary.

Additional research supports the statement that personal exposure due to NFC devices are below the basic restrictions of safety guidelines.

To conclude, the NFC RF Module, used e.g. in the CNAP Hand Module (PC6510), fulfills the acceptance criteria of FCC regarding human exposure.