

TEST REPORT

No.: 21-1-0179501T10a-C02

According to:
KDB 447498 D01
General RF Exposure Guidance

FCC Regulations
§1.1310
§ 2.1091 & 2.1093

for
Sentec AG

Patient Monitor
tCOM+

Laboratory Accreditation



accredited according to DIN EN ISO/IEC 17025:2018

cetecom advanced GmbH
Laboratory Radio Communications & Electromagnetic Compatibility
Im Teelbruch 116 • 45219 Essen • Germany
Registered in Essen, Germany, Reg. No.: HRB Essen 8984
Tel.: + 49 (0) 20 54 / 95 19-0 • Fax: + 49 (0) 20 54 / 95 19-150
E-mail: contact@cetecomadvanced.com • Internet: www.cetecomadvanced.com

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1. Summary of test results

The test results apply exclusively to the test samples as presented in this Report. The CETECOM GmbH does not assume responsibility for any conclusions and generalizations taken in conjunction with other specimens or samples of the type of the item presented to tests.

The Equipment Under Test (in this report, hereinafter referred as EUT) is a RFID Reader
The device is operated at Carrier Frequency 13.56 MHz

TEST OVERVIEW

EMF Phenomenon	Test Cases	Port	References, Standards & Limits		EUT set-up	EUT op-mode	Result
			FCC	Limits			
RF Exposure E-Field	Electric field strength	20cm distance center of probe to EUT	§1.1310 §2.1091 §2.1093	60.76 (V/m)	1	1	passed
RF Exposure H-Field	Magnetic field strength	20cm distance center of probe to EUT	§1.1310 §2.1091 §2.1093	0.16 (A/m)	1	1	passed

The current version of Test Report 21-1-0179501T10a-C02 replaces the test report 21-1-0179501T10a_C01 dated 2023-Jul-04. The replaced test report is herewith invalid.



.....
Dipl.-Ing. Ninovic Perez
Responsible for test section



.....
Wolfgang Markus
Responsible for test report

2. Administrative Data

2.1. Identification of the testing laboratory

Company name:	CETECOM GmbH
Address:	Im Teelbruch 116 45219 Essen - Kettwig Germany
Responsible for testing laboratory:	Dipl.-Ing. Ninovic Perez

2.2. Test location

2.2.1. Test laboratory

Company name:	see chapter 2.1. Identification of the testing laboratory
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2.3. Organizational items

Responsible for test report:	W. Markus
Receipt of EUT:	2023-May-03
Date(s) of test:	2023-Jun-30
Date of report:	2023-Jul-05

2.4. Applicant's details

Applicant's name:	Sentec AG
Address:	Ringstrasse 39 4106 Therwil Switzerland
Contact person:	Oliver Friedli oliver.friedli@sentec.com

2.5. Manufacturer's details

Customer's name:	same as applicant.
Address:	same as applicant

3. Equipment under test (EUT)

3.1. Technical data of main EUT declared by applicant

3.2. EUT: Type, S/N etc. and short descriptions used in this test report

Short description*)	EUT	Model	Type	S/N serial number	HW hardware status	SW software status
EUT A (S36)	Patient Monitor	tCOM+	n/a	000032	103164 0001E	V00.01.03

*) EUT short description is used to simplify the identification of the EUT in this test report.

3.3. Auxiliary Equipment (AE): Type, S/N etc. and short descriptions

AE short description *)	Auxiliary Equipment	Model	Type	S/N serial number	HW hardware status	SW software status
AE 1 (S40)	Power Supply	n/a	n/a	n/a	n/a	n/a

*) AE short description is used to simplify the identification of the auxiliary equipment in this test report.

3.4. EUT set-ups

EUT set-up no. *)	Combination of EUT and AE	Remarks
Set. 1	EUT A + AE1	--

*) EUT set-up no. is used to simplify the identification of the EUT set-up in this test report.

3.5. EUT operating modes

EUT operating mode no. *)	Description of operating modes	Additional information
op. 1	TX RFID 13.56 MHz	Due to test mode SW EUT is continuously sending a modulated carrier signal

*) EUT operating mode no. is used to simplify the test report.

3.6. Additional declaration and description of EUT

Set up 1	☐ table-top ☐ floor-standing ☐ wall-mounted ☒ not defined	typical use ☒ portable use ☐ fixed use ☐ vehicular use	
Place of use	☒ Residential, commercial and light industry ☐ Industrial environment ☐ vehicular use		
typical operating cycle of EUT	☐ < 0.5 sec. ☐ :		
Power line: ☒ AC ☒ 120 V, ☐ 230 V, ☐ 400 V ☐ PE, ☐ N, ☐ L1, ☐ L2 ☐ L3 ☐ ___ Hz ☐ DC ☐ 12.0V	EUT-grounding: ☒ none ☐ with power supply ☐ additional: (in case of deviation during tests the single details are described on chapter 4)		
Other Ports (description of interconnecting cables) Description	possible total cable length	shielding	connected during test
1. DC supply	☒ < 3 m ☐ > 3 m ☐ : other	☐ screened ☒ unscreened	☒ yes ☐ no
Does EUT contain devices susceptible to magnetic fields, e.g. Hall elements, electrodynamics microphones, etc.?			☐ yes ☒ no
Is mounting position / usual operating position defined?			☐ yes ☒ no

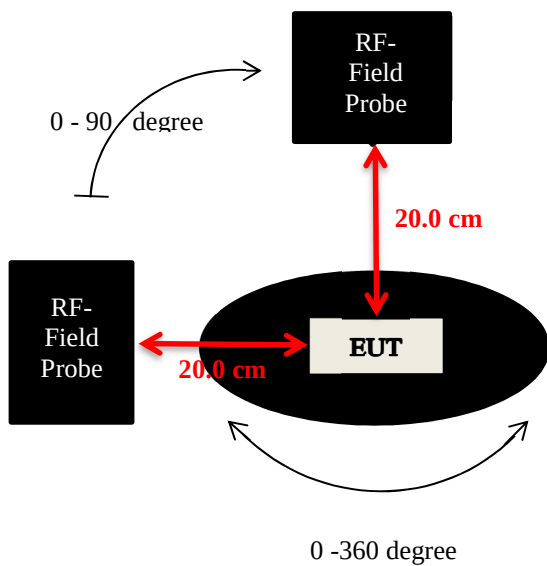
4. DESCRIPTION OF TEST SET-UP's

4.1. Test Set-up for configuration

The RF exposure test is performed in shielded room.

The EUT was placed on a table.

The measurement probe was moved at a distance of 20 cm to the EUT and the table was rotated 360 degrees around the EUT to maximize the captured field strength.



Schematic: Test set-up for RF exposure measurements

Measurement for E-Field in frequency range
100 kHz – 6 GHz with NBM 550 + Probe EF 0691

Measurement for H-Field in frequency range
300 kHz – 30 MHz with NBM 550 + Probe HF 3061

5. Maximum Permissible RF Exposure

5.1 KDB 447498 D01 General RF Exposure Guidance RF Exposure Limits

Table 1 – RF Exposure Limits in FCC Rules and OET Equipment Authorization Policies

Frequency range ^a	FCC Rules	OET Equipment Authorization Policies
$f \leq 100$ kHz	N/A (under consideration) ^c	All devices assessed case-by-case, with field strength limits of $E = 83$ V/m and $H = 90$ A/m, in all body exposure relevant positions
$100 \text{ kHz} < f \leq 300 \text{ kHz}$ ^b	SAR limits in § 1.1310 (b), (c)	MPE limits at 300 kHz in Table 1 to § 1.1310(e)(1): $E = 614$ V/m and $H = 1.63$ A/m
$300 \text{ kHz} < f \leq 4 \text{ MHz}$ ^b	§ 2.1091 Mobile Devices: MPE limits in Table 1 to § 1.1310(e)(1) ^d	MPE limits in Table 1 to § 1.1310(e)(1)
	§ 2.1093 Portable Devices: SAR limits in § 1.1310 (b), (c)	
$4 \text{ MHz} < f \leq 6 \text{ GHz}$	§ 2.1091 Mobile Devices: MPE limits in Table 1 to § 1.1310(e)(1) ^d	
	§ 2.1093 Portable Devices: SAR limits in § 1.1310 (b), (c)	
$6 \text{ GHz} < f \leq 100 \text{ GHz}$	MPE limits in Table 1 to § 1.1310(e)(1) ^c	
$100 \text{ GHz} < f \leq 3000 \text{ GHz}$	N/A (under consideration) ^c	
^a For all $f \leq 6$ GHz, SAR limits in §§ 1.1310 (b), (c) can always be applied where available, in place of MPE limits		
^b Policies for $100 \text{ kHz} < f \leq 4 \text{ MHz}$ reflect capabilities of a available SAR measurement equipment. Numerical simulations may be also acceptable, and are considered under PAG per KDB Pub. 388624		
^c NPRM, ET Docket No. 19-226; FCC 19-126, 34 FCC Rcd 11743		
^d Per § 2.1091 (d)(4) SAR limits are applicable in some cases		

5.2 FCC References & Limits

FCC Rules: §1.1310, § 2.1093

The criteria used for the evaluation of human exposure to radio frequency radiation is listed in table 1 according FCC §1.1307(b), except in the case of portable devices which shall be evaluated according to the provisions of §2.1093 of this.

Note 1 to table 1: Occupational/controlled limits apply in situations in which persons are exposed as a consequence of their employment provide those persons are fully aware for a exposure and can control over their exposure. Limits for occupational/controlled exposures also apply in situations when an individual is transient through a location where occupational/controlled apply provided he or she is made aware of the potential for exposure.

Note 2 to table 1: General population/uncontrolled exposures apply in situations in which the general public may be exposed, or which persons that are exposed as a consequence of their employment may not be fully aware of the potential for exposure or cannot exercise control over their exposure.

TABLE 1—LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)—Continued

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ²)	Averaging time (minutes)
30–300	61.4	0.163	1.0	6
300–1500			f/300	6
1500–100,000			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
300–1500			f/1500	30
1500–100,000			1.0	30

f = frequency in MHz

So applicable limits in this case are as follows:

§1.1310 LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Table 1(B) Limits for General Population/Uncontrolled Exposure

1.34 - 30 MHz: Electric field: 60.76 V/m

1.34 - 30 MHz: Magnetic field: 0.16 A/m

6. E-Field Results

6.0.1. Test location and equipment (for reference numbers please see chapter 'List of test equipment')

test location	☒ CETECOM Essen (Chapter 2.2.1)	☐ Please see Chapter 2.2.2	☐ Please see Chapter 2.2.3
equipment	☒ 20847 NBM 550	☒ 20848 EF 0391	☐ ☐
signaling	☐ 017 CMD 65	☐ 323 CMD 55	☐ 340 CMD 55
signaling	☐ 298 CMU	☐ 460 CMU	☐ 295 RACAL
line voltage	12.0 V DC	☐ 392 MT8820A	

6.0.2. Test condition and test set-up

link to test system (if used):	☐ air link	☐ cable connection	
EUT-grounding (if different to chapter 3.5)	☐ none	☐ with power supply	☐ additional connection
Equipment set up	-	-	-
Climatic conditions	Temperature: 22 °C	Rel. humidity: 41% rH	

EUT Type and S/N or EUT set-up no.		EUT set-up 1		
EUT operating mode or operating mode no.		EUT operating mode 1		
Frequency Range (MHz)	Distance between EUT and Field probe (m)	E-field *) (V/m)	E-field Limit (V/m)	Result
100 kHz – 6 GHz	0.2 (worst case position)	0.60	60.76	passed

Remark *): The electric field strength is measured under max-hold mode.

6.1. H-Field Results

6.1.1. Test location and equipment (for reference numbers please see chapter 'List of test equipment')

test location	☒ CETECOM Essen (Chapter 2.2.1)		☐ Please see Chapter 2.2.2		☐ Please see Chapter 2.2.3	
equipment	☒ 20847 NBM 550	☒ 20849 HF 3061	☐ 20850 EHP-50	☐	☐	☐
signaling	☐ 017 CMD 65	☐ 323 CMD 55	☐ 340 CMD 55			
signaling	☐ 298 CMU	☐ 460 CMU	☐ 295 RACAL	☐ 392 MT8820A		
line voltage	12.0 V DC					

6.1.2. Test condition and test set-up

link to test system (if used):	☐ air link	☐ cable connection	
EUT-grounding (if different to chapter 3.5)	☐ none	☐ with power supply	☐ additional connection
Equipment set up	-		
Climatic conditions	Temperature: 22 ° C		Rel. humidity: 41% rH

6.1.3. Results

EUT Type and S/N or EUT set-up no.		EUT set-up 1		
EUT operating mode or operating mode no.		EUT operating mode 1		
Frequency Range (MHz)	Distance between EUT and Field probe (m)	H-field*) (A/m)	H-field Limit (A/m)	Result
300 kHz – 30 MHz	0.02 (worst case position)	0.006	0.16	passed

Remark *): The magnetic field strength is measured under max-hold mode.

6.1.4. Measurement uncertainties

The reported uncertainties are calculated based on the standard uncertainty multiplied with the appropriate coverage factor **k**, such that a confidence level of approximately 95% is achieved.

For uncertainty determination, each component used in the concrete measurement set-up was taken in account and its contribution to the overall uncertainty according to its statistical distribution calculated.

Following table shows expectable uncertainties for each measurement type performed.

RF-Measurement	Frequency range	Calculated uncertainty based on a confidence level of 95%	Remarks:
Power Output conducted	9 kHz .. 20 GHz	1.0 dB	--
Power Output radiated	30 MHz .. 4 GHz	3.17 dB	Substitution method
Conducted emissions on antenna ports	9 kHz .. 20 GHz	1.0 dB	--
Radiated emissions enclosure	9 kHz .. 30 MHz	5.0 dB	Magnetic field
	9 MHz .. 1 GHz	5.0 dB	E-Field
	30 MHz .. 1 GHz	4.2 dB	E-Field
	1 GHz .. 20 GHz	3.17 dB	Substitution method
Occupied bandwidth	9 kHz .. 4 GHz	0.1272 ppm (Delta Marker)	Frequency error
		1.0 dB	Power
Emission bandwidth	9 kHz .. 4 GHz	0.1272 ppm (Delta Marker)	Frequency error
		1.0 dB	Power
Frequency stability	9 kHz .. 20 GHz	0.0636 ppm	--
Conducted emissions on AC-mains port (UCISPR)	9 kHz .. 150 kHz	4.0 dB	--
	150 kHz .. 30 MHz	3.6 dB	--

Table: measurement uncertainties, valid for conducted/radiated measurements

7. Accreditation details of CETECOM's laboratories and test sites

Ref.-No.	Accreditation Certificate	Valid for laboratory area or test site	Accreditation Body
-	D-PL-12047-01-01	All laboratories and test sites of CETECOM GmbH, Essen	DAkkS, Deutsche Akkreditierungsstelle GmbH
337 487 558 348 348	MRA US-EU 0003	Radiated Measurements 30 MHz to 1 GHz, 3 m / 10 m (OATS) Radiated Measurements 30 MHz to 1 GHz, 3 m (SAR) Radiated Measurements above 1 GHz, 3 m (FAR) Mains Ports Conducted Interference Measurements Telecommunication Ports Conducted Interference Measurem.	FCC, Federal Communications Commission Laboratory Division, USA (MRA US-EU 0003)
337 487 550 558	3462D-1 3462D-2 3462D-2 3462D-3	Radiated Measurements 30 MHz to 1 GHz, 3 m / 10 m (OATS) Radiated Measurements 30 MHz to 1 GHz, 3 m (SAR) Radiated Measurements 1 GHz to 6 GHz, 3 m (SAR) Radiated Measurements above 1 GHz, 3 m (FAR)	IC, Industry Canada Certification and Engineering Bureau
337 487 550 348	R-20013 G-20013 C-20009 T-20006	Radiated Measurements 30 MHz to 1 GHz, 3 m (SAR) Radiated Measurements 1 GHz to 6 GHz, 3 m (SAR) Mains Ports Conducted Interference Measurements Telecommunication Ports Conducted Interference Measurem.	VCCI, Voluntary Control Council for Interference by Information Technology Equipment, Japan
OATS = Open Area Test Site, SAR = Semi Anechoic Room, FAR = Fully Anechoic Room			

8. Instruments and Ancillary

8.1. Used equipment

The “Ref.-No” in the left column of the following tables allows the clear identification of the laboratory equipment.

8.1.1. Single instruments and test systems

Ref.-No.	Equipment	Type	Serial-No.	Manufacturer	Interval of calibration	Remark	Cal due
20616	Digitalmultimeter	Fluke 177	88900339	Fluke	24 M	--	01.06.2024
20847	Broadband Field Meter	NBM 550	H-0929	Narda Safety Test Solution	24 M	--	14.04.2024
20848	E-Field Probe	EF 0391	H-0851	Narda Safety Test Solution	24 M	--	14.04.2024
20849	H-Field Probe	HF 3061	D-0805	Narda Safety Test Solution	24 M	--	14.04.2024

9. Versions of test reports (change history)

Version	Applied changes	Date of release
--	Initial release	2023-Jul-03
C01	Some corrections of wording and frequency range	2023-Jul-04
C02	Separated photographs to new annex document 3 and 4. Added table of annex to page 2.	2023-Jul-05
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End of Test Report