

TEST RESULT SUMMARY

FCC PART 15 SUBPART C

Section 15.209 Radiated Emission Requirements

MANUFACTURER'S NAME

Data Sciences International, Incorporated

NAME OF EQUIPMENT

Mouse Blood Pressure Implant

Mouse Biopotential and Temperature Implant

Mouse Biopotential Implant Mouse Temperature Implant

MODEL NUMBER TA11PA-C20

TA10ETA-F20 TA10EA-F20 TA10TA-F20

MANUFACTURER'S ADDRESS 4211 Lexington Avenue North, Suite 2244

St. Paul MN 55126

TEST REPORT NUMBER NC107204

TEST DATE 31 October 2001

According to testing performed at TÜV Product Service Inc, the above-mentioned unit is in compliance with the electromagnetic compatibility requirements defined in FCC Part 15 Subpart C, Section 15.209.

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

TÜV Product Service Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the requirements of FCC Part 15 Subpart C, Section 15.209.

Date: 13 November 2001

Location: Taylors Falls MN

USA

J. C. Sausen Test Engineer J. T. Schneider Chief Engineer

CSausan Joel T. Dohneise

Not Transferable



EMC EMISSION - TEST REPORT

Test Report File No.	:	NC107204	Date of issue:	13 November 2001		
Model / Serial No.	:	TA11PA-C20 / 20	_			
		TA10ETA-F20 / 5143 TA10EA-F20 / 5881				
		TA10TA-F20 / 69				
Product Type	:	Mouse Blood Pre				
		Mouse Biopotent Mouse Biopotent	•	ature impiant		
		Mouse Temperat				
Applicant	<u>:</u>	Data Sciences In	ternational, Inco	orporated		
Manufacturer		Data Sciences In	ternational Inco	ornorated		
Manadard	<u> </u>	Data Ociences III	terriational, ince	orporated		
License holder	:	Data Sciences In	ternational, Inco	orporated		
Address	:	4211 Lexington A	venue North, S	uite 2244		
	:	St. Paul MN 5512	26			
Test Result	:	■ Positive □	l Negative			
Test Project Number	:					
Reference(s)		NC107204				
Total pages including						
Appendices		21				
TÜN Product Sorvice Inc. is a subcentra	otor to TÜV	Product Sorvice CmbH accord	ing to the principles outline	d in ISO/IEC Guido 25 and EN		

TÜV Product Service Inc is a subcontractor to TÜV Product Service, GmbH according to the principles outlined in ISO/IEC Guide 25 and EN 45001.

TÜV Product Service Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV Product Service Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV Product Service Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. This report shall not be used by the client to claim product endorsement by NVLAP or any agency of the US government.

TÜV Product Service Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NVLAP, and VCCI



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EMISSIONS TEST REGULATIONS:

The emissions tests were performed according	to following regulations:	
□ - EN 50081-1 / 1991 □ - EN 55011 / 1991	□ - Group 1 □ - Class A	□ - Group 2 □ - Class B
□ - EN 55013 / 1990 □ - EN 55014 / 1987	☐ - Class A ☐ - Household applia ☐ - Portable tools ☐ - Semiconductor de	nces and similar
□ - EN 55014 / A2:1990 □ - EN 55014 / 1993	☐ - Household applia☐ - Portable tools☐ - Semiconductor de	
□ - EN 55015 / 1987 □ - EN 55015 / A1:1990 □ - EN 55015 / 1993 □ - EN 55022 / 1987	□ - Class A	□ - Class B
□ - EN 55022 / 1994 □ - BS	□ - Class A	□ - Class B
□ - VCCI ■ - FCC Part 15 Subpart C, Section 15.209 □ - FCC Part 15 Subpart B	□ - Class A □ - Class A	□ - Class B □ - Class B
□ - CISPR 11 (1990) □ - CISPR 22 (1993)	□ - Group 1 □ - Class A □ - Class A	□ - Group 2 □ - Class B □ - Class B
()		



Environmental conditions in the lab:

<u>Actual</u> : 22 °C Temperature Relative Humidity : 30 % Atmospheric pressure : 98.1 kPa

Power supply system : 1.5 VDC - Battery

Sign Explanations:

□ - not applicable■ - applicable



CONDUCTED EMISSIONS (15.207)

Conducted emissions 450 kHz - 30 MHz				
The requirements are	□ - MET	□ - N	OT MET	■ - N/A
Minimum margin of compliance	dB	at	MHz	
The CONDUCTED EMISSIONS (INTERFERENCE VOLTAGE)	measurements were	performed a	t the following	g test location:

☐ - Wild River Lab Large Test Site (Open Area Test Site)

■ - Test Not Applicable

Conducted emissions on the 60 Hz power interface of the EUT are measured in the frequency range of 450 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth and quasi-peak detection, and a Line Impedance Stabilization Network (LISN), with 50 Ω/50 μH (CISPR 16) characteristics. In some cases, a pre-scan using a spectrum analyzer is initially performed on the units comprising the system under test to locate the highest emissions. If the minimum passing margin appears to be less than 20 dB with a peak mode measurement, the emissions are re-measured using a tuned receiver or spectrum analyzer with quasi-peak and average detection and recorded on the data sheets. The final measurement is taken off of the receiver, which has the LISN insertion loss, cable loss, and 10 dB attenuator factors stored in memory.



RADIATED EMISSIONS (15.209 - 10 kHz to 30 MHz)

Radiated emissions 10 kHz - 30 MHz				
The requirements are	■ - MET		- NOT MET	
Minimum limit margin for fundamental	84 dB	at	455.0 kHz	
Minimum limit margin for harmonics/spurious	<u>>10</u> dB	at	MHz	
No signals could be detected from the eut at a 3 meter	antenna distance. Mea	asurement	s were made at 0.3 and	1 meters
in order to establish the falloff rate of the measured sign	hals, and this rate was i	ised to ex	trapolate the measured v	alues out

The RADIATED EMISSIONS (10 KHZ TO 30 MHZ) measurements were performed at the following test location:

■ - Wild River Lab Large Test Site (Open Area Test Site)

at a test distance of:

to 30 or 300 meters, as appropriate.

- - .3 meters
- - 1 meters
- - 3 meters

Test equipment used:

	TUV ID	Model Number	Manufacturer	Description	Serial Number	er Cal Due
■ -	2517	HFH2-Z2	Polarad	Loop Antenna	879285/036	2-01-02
■ -	2534	ESHS-20	Rhode & Schwarz	EMI Receiver	837055/003	8-22-02

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST) and is calibrated annually.

In the frequency range of 10 kHz to 30 MHz, a shielded loop antenna is positioned with its plane vertical at 0.3 and 1 meters from the EUT and rotated about its vertical axis for maximum response at each azimuth about the EUT. The loop antenna is also positioned horizontally. The center of the loop antenna is 1 meter above the ground plane. Since the measurements were well within the requirements, the unit was not remeasured off of the ground plane. Measurements between 9 kHz and 30 MHz are made with 9 kHz/6 dB bandwidth and quasi-peak or average detection with a receiver.

RADIATED EMISSIONS DATA

							15.209	
	dBuV/m	dBuV/m	dBuV/m	dBuV/m	dBuV/m	300 meters	300 m spec limit	margin
MHz	0.3 meter	1 meter	3 meters	10 meters	30 meters	dBuV/m	dBuV/m	dB
0.455	53	32.5	12	-8.5	-29	-70	14.4439969	84.444

Average Measurement at 455.0 kHz, no duty cycle correction factor applied.

Tested Models TA11PA-C20, TA10ETA-F20, TA10EA-F20, TA10TA-F20

Worst case data presented above is from the Model TA10EA-F20. Test results

listed are with modulation producing highest emission levels.

Levels at 0.3, 1 meter are measured - other levels are extrapolated.

No other significant emissions detected 9 kHz to 30 MHz.

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TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758

Tel: 651 638 Fax: 651 638 0297

0298

Rev.No 1.0



Emissions Test Conditions: RADIATED EMISSIONS (30-1000 MHz)

The RADIATED EMISSIONS (ELECTRIC FIELD) measurements, in the frequency range of 30 MHz-1000 MHz, were tested in a horizontal and vertical polarization at the following test location:

■ - Wild River Lab Large Test Site (Open Area Test Site) – NSA measurements made 7-01, due 7-02

at a test distance of:

■ - 3 meters – no signals detected from the transmitter within 10 dB of the limit.

Test equipment used :

	TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
■ -	3202	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	9-24-02
■ -	2865	11867A	Hewlett-Packard	Limiter	01972	3-21-02
■ -	2690	8566B	Hewlett-Packard	Spectrum Analyzer (Unit F)	2430A00930	11-16-01
■ -	2678	85662A	Hewlett-Packard	Analyzer Display (Unit F)	2403A08134	11-16-01
■ -	2684	85650A	Hewlett-Packard	Quasi-Peak Adapter (Unit F)	2521A01006	11-24-01
■-	2665	ZHL-1042J	Mini-Circuits	Preamplifier	32296	9-12-02

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST) and is calibrated annually.

Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with 120 kHz/6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz/6 dB bandwidth and peak detection. Table top equipment is placed on a 1.0 X 1.5 meter non-conducting table 80 centimeters above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT are rotated 360 degrees. The final level, expressed in dB μ V/m, is arrived at by taking the reading from the spectrum analyzer (Level dB μ V) and adding the antenna correction factor and cable loss factor, and subtracting the preamplifier gain, to it.

Exampl	e:
--------	----

FREQ	LEVEL	CABLE/ANT/PREAMP	FINAL	POL/HGT/AZ	DELTA1
(MHz)	(dBuV)	(dB) (dB/m) (dB)	(dBuV/m)	(m) (deg)	
79.06	40.7Qp +	1.9 + 6.6 - 28.3 =	20.9	V 1.0 0.0	-9.1



Equipment Under Test (EUT) Test Operation Mode - Emission tests: The device under test was operated under the following conditions during emissions testing: □ - Standby ☐ - Test program (H - Pattern) ☐ - Test program (color bar) □ - Test program (customer specific) ☐ - Practice operation ■ - Normal Operating Mode Configuration of the device under test: ■ - See Constructional Data Form in Appendix B - Page B2 □ - See Product Information Form in Appendix B - beginning on Page B3 The following peripheral devices and interface cables were connected during the measurement: Type : _____ Type: Type: □-Type : _____ Type : _____ Type : ___ Type : _____ □ - unshielded power cable □ - unshielded cables MPS.No.: _____ □ - shielded cables ☐ - customer specific cables O-____ □-



DEVIATIONS FROM STANDARD:			
None.			
GENERAL REMARKS:			
The radiated measurements from 10 kHz to between 110-490 kHz, which are made in a	30 MHz are made in quasi-peak detection, except for the levels noted verage detection.		
SUMMARY:			
The requirements according to the tech	nical regulations are		
■ - met			
□ - not met.			
The device under test does			
■ - fulfill the general approval requirem	ents mentioned on page 3.		
□ - not fulfill the general approval requ	irements mentioned on page 3.		
Testing Start Date:	31 October 2001		
Testing End Date:	31 October 2001		
- TÜV PRODUCT SERVICE INC -			
Joel T. Sohneiser	JC Sausan		
J. T. Schneider Chief Engineer	Tested By: J. C. Sausen		



Test-setup photo(s): Conducted emission 10/150 kHz - 30 MHz

Not Applicable





Test-setup photo(s): Radiated emission 10 kHz - 1000 MHz





Appendix A

Constructional Data Form





PLEASE COMPLETE TH	PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE.			
	nis information will be input into your test i ime to get HELP for the current field select		n below.	
Company:	Data Sciences Intl. Inc.			
Address:	4211 Lexington Ave. N. Suite 224	4		
	St. Paul, Minnesota 55126-6164			
Contact:	Perry Mills	Position:	СТО	
Phone:	651-481-7421	Fax:	651-481-7416	
E-mail Address:	pmills@datasci.com			
General Equipment	Description NOTE: This information	will be input int	o your test report as shown below.	
EUT Description	a) Mouse Blood Pressure Implant b) Mouse Biopotential and Tempera c) Mouse Biopotential Implant d) Mouse Temperature Implant			
EUT Name	a) Mouse Blood Pressure Implantb) Mouse Biopotential and Temperac) Mouse Biopotential Implantd) Mouse Temperature Implant	ature Implant		
Model No.:	a) TA11PA-C20 b) TA10ETA-F20 c) TA10EA-F20 d) TA10TA-F20	Serial No.:	a) 2014 b) 5143 c) 5881 d) 6933	
Product Options:	None			
Configurations to be t	ested: Standard			
Tool Oh institut				
Test Objective EMC Directive 89/	336/EEC (EMC)	C: Clas	ss 🛛 A 🗌 B Part 15	
Std: □ VCCI: Class □ A □ Machinery Directive 89/392/EEC (EMC) □ BSMI: Class □ A □ Std: □ Canada: Class □ A □ Medical Device Directive 93/42/EEC (EMC) □ Australia: Class □ A □ Std: □ Other:				
Vehicle Directive 72/245/EEC (EMC) Std: FDA Reviewers Guidance for Premarket Notification Submissions (EMC)				



TÜV Product Service Certification Requested
☐ Attestation of Conformity (AoC) ☐ EMC Certification (used with Octagon Mark)
☐ Certificate of Conformity (CoC) ☐ Compliance Document
Protection Class (N/A for vehicles)
(Press F1 when field is selected to show additional information on Protection Class.)
Attendance
Test will be: Attended by the customer Unattended by the customer
Failure - Complete this section if testing will not be attended by the customer.
If a failure occurs, TUV Product Service should: Call contact listed above, if not available then stop testing. (After hrs phone):
Continue testing to complete test series.Continue testing to define corrective action.
Stop testing.
EUT Specifications and Requirements
Length: 2.5 cm Width: 1.5 cm Height: 1.0 cm Weight: 3.5 grams
Power Requirements
Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)
Voltage: 1.5 volt (battery powered, make sure battery life is sufficient to complete testing.) powered)
of Phases:
Current Current (Amps/phase(max)): < 25uA (Amps/phase(nominal)):
Other
Other Special Requirements
N/A
Typical Installation and/or Operating Environment
(ie. Hospital, Small Business, Industrial/Factory, etc.) animal laboratory in industry, hospital, or academia
EUT Power Cable
Permanent OR Removable Length (in meters):
☐ Shielded OR ☐ Unshielded☑ Not Applicable



EUT Interface Ports and Cables												
Interface				Shielding								
Туре	Analog	Digital	Qty	Yes	2	Туре	Termination	Connector Type	Port Termination	Length (in meters)	Removable	Permanent
EXAMPLE: RS232		×	2	×		Foil over braid	Coaxial	Metallized 9- pin D-Sub	Characteristic Impedance	6	×	
N/A						r on over grand	Coaxia			- U		



EUT Software.							
Revision Level: N/A							
Description:							
Equipment Under Test (EUT) Operating Modes to be Tested list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.							
1. Normal (on)							
2.							
3.							
Equipment Under Test (EUT) System Components List and describe all components which are part of the EUT. For FCC testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc.)							
Description	Model #	Serial #	FCC ID #				
implant only							



Support Equip	oment List	and describe	e all support equipm	ent which is not part	of the EUT. (i.e. peripherals, simulators, etc)			
Description		Mode	el #	Serial #	FCC ID #			
AM broadcast receiver to verifiy operation of the implant								
Oscillator Frequencies								
_	Derived							
Frequency	Frequency	Com	ponent # / Location	1	Description of Use			
0.2 to 1.0 kHz								
					1			
Power Supply								
Manufacturer	Model #	ŧ	Serial #	Туре				
N/A				Switched-				
				Linear	Other:			
				Switched-	· · · · —			
_				Linear	Other:			
Power Line Fil	Iters							
Manufacturer		Model #		Location in EUT				
				23041011 111 201				
N/A								



Description	Manufacturer	Part # or Value	Qty	Component # / Location
None				
EMC Critical Deta	ail Describe other EMC Design	details used to reduce hig	gh frequency	/ noise.
N/A				
14// (
(PLEASE INSER	T"ELECTRONIC SIGNATU	RE " BELOW IF POS	SSIBLE)	
Authorization Sig			ļ	
Daws Milla				
Perry Mills		10/26/0	1	
	orization to perform tests is test plan.	10/26/0 Date	1	
Customer auth				
Customer auth according to the Perry Mills		Date		
Customer auth according to the Perry Mills	is test plan.	Date 10/26/0		

EMC Block Diagram Form



System Configuration Block Diagram Provide a line cables, power cables, and any other pertinent components to be us equipment in the testing field versus equipment outside testing field	ed during testing. Use a dashed line to separate the
AM Broadcast receiver to operation of implant (trans	
Authorization Signatures	
Perry Mills	10/26/01
Customer authorization to perform tests according to this test plan.	Date
Perry Mills	10/26/01
Test Plan/CDF Prepared By (please print)	Date
Reviewed by TÜV Product Service Associate	Date



Appendix B

MEASUREMENT PROTOCOL FOR FCC

GENERAL INFORMATION

Test Methodology

Conducted and radiated emission testing is performed according to the procedures in International Special Committee on Radio Interference (CISPR) Publication 22 (1993), European Standard EN 55022 and Australian Standard AS 3548 (which are based on CISPR 22).

The Japanese standard, "Voluntary Control Council for Interference (VCCI) by Data Processing Equipment and Electronic Office Machines, Technical Requirements" is technically equivalent to CISPR 22 (1993). For official compliance, a conformance report must be sent to and accepted by the VCCI.

In compliance with FCC Docket 92-152, "Harmonization of Rules for Digital Devices Incorporate International Standards", testing for FCC compliance may be done following the ANSI C63.4-1992 procedures and using the CISPR 22 Limits.

Measurement Uncertainty

The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. These test systems have a measurement uncertainty of ±4.5 dB. The equipment comprising the test systems are calibrated on an annual basis.

Justification

The Equipment Under Test (EUT) is configured in a typical user arrangement in accordance with the manufacturer's instructions. A cable is connected to each available port and either terminated with a peripheral into it's characteristic impedance or left unterminated. When appropriate, the cables are manually manipulated with respect to each other to obtain maximum emissions from the unit.

CONDUCTED EMISSIONS

The final level, expressed in dBµV, is arrived at by taking the reading directly from the EMI receiver. This level is compared directly to the FCC limit.

To convert between $dB\mu V$ and μV , the following conversions apply:

 $dB\mu V = 20(log \mu V)$ $\mu V = Inverse log(dB\mu V/20)$

RADIATED EMISSIONS

The final level, expressed in dBμV/m, is arrived at by taking the reading from the spectrum analyzer (Level dBμV) and adding the antenna correction factor and cable loss factor, and subtracting the preamplifier gain, to it. This result then has the duty cycle correction factor subtracted from it to provide the final average reading.

Example:

FREQ	LEVEL	CABLE/ANT/PREAMP	FINAL	POL/HGT/AZ	DELTA1
(MHz)	(dBuV)	(dB) (dB/m) (dB)	(dBuV/m)	(m) (deg)	
79.06	40.7Qp +	1.9 + 6.6 - 28.3 =	20.9	V 1.0 0.0	-9.1

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DETAILS OF TEST PROCEDURES

General Standard Information

The test methods used comply with ANSI C63.4-1992 - "Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz."

Conducted Emissions

Conducted emissions on the 60 Hz power interface of the EUT are measured in the frequency range of 450 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth and quasi-peak detection, and a Line Impedance Stabilization Network (LISN), with $50~\Omega/50~\mu H$ (CISPR 16) characteristics. Table top equipment is placed on a non-conducting table 80 centimeters above the floor and is positioned 40 centimeters from the vertical ground plane (wall) of the screen room. In some cases, a pre-scan using a spectrum analyzer is initially performed on the units comprising the system under test to locate the highest emissions. If the minimum passing margin appears to be less than 20 dB with a peak mode measurement, the emissions are re-measured using a tuned receiver or spectrum analyzer with quasi-peak and average detection and recorded on the data sheets.

Radiated Emissions

Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with 120 kHz/6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz/6 dB bandwidth and peak detection. Table top equipment is placed on a 1.0 X 1.5 meter non-conducting table 80 centimeters above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT are rotated 360 degrees. Intentional radiators are rotated through three orthogonal axes to determine the attitude that maximizes the emissions.

In the frequency range of 10 kHz to 30 MHz, a shielded loop antenna is positioned with its plane vertical at 0.3 and 1 meters from the EUT and rotated about its vertical axis for maximum response at each azimuth about the EUT. The loop antenna is also positioned horizontally. The center of the loop antenna is 1 meter above the ground plane. Since the measurements were well within the requirements, the unit was not remeasured off of the ground plane. Measurements between 9 kHz and 30 MHz are made with 9 kHz/6 dB bandwidth and quasi-peak detection with a receiver.