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Test report #498ENV12

Measurements and test for device safety on the devices/equipment:

Sensors for pulsoximeters

Test item:

Description: Sensors for pulsoximeters
Model: Finger probe
Serial number: as per type table

Distributor: EnviteC Wismar GmbH
Philipp-Müller-Straße 12
23966 Wismar

Testing laboratory:

EMV-Informations- und Prüfbzentrum e.V.
Philipp-Müller-Straße 12
23966 Wismar

Test specification:

Device safety:	Patient discharge currents	
	High-frequency electromagnetic field	DIN EN 60601-1 /03.96/
	Strike and creep distances	DIN EN 60601-1 /03.96/

Test period: 19./20. January 1998

This report contains 6 pages, including appendices.

Note:

EMC-IPZ e. V. guarantees those commissioning the test that the tests were carried out in accordance with the scope of the test as detailed under point 2 and the test specifications detailed under point 3. Any deviations are presented separately.

The test results contained in this test report relate exclusively to the testing of the test item presented. EMC-IPZ e. V. accepts no liability for consequences and generalizations which may subsequently be drawn from the test results for further prototypes and models of the device type represented by the test item.

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1. General information on the test item(s)

Description:	Sesors for pulsoximeters
Model:	Sensors for the devices from Nellcor, Ohmeda, Datex, MCI, Novamatrix and Datascope
Serial number:	as per type table
Distributor:	EnviteC Wismar GmbH
Contact person:	Herr Scholl

Brief description: These sensors are accessories for the pulsoximeters from the companies Nellcor, MCI, Ohmeda, Datex, Novamatrix and Datascope. With the help of the sensors it is possible to record the pulse and the oxygen content of the blood. When doing so, different application points can be selected, such as ear, finger and foot.

Participant in the test: Herr Scholl (EnviteC Wismar)

Responsible for the technical content of the report:

	Name	Signature
Tester	Reiko Witt	
Engineer responsible	Reiko Witt	

2. Scope of tests

The tests were carried out following the applicable regulations on standards contained in DIN EN 60601-1 /03.96/. They are regarded as pre-tests for the assessment of device safety.

2.1 Patient discharge currents

DIN EN 60601-1 /March 1996/ para.19

Medical electrical devices

Part 1: General restrictions for safety

The sensors were ranked by CF as application part. As such they are subject to additional regulations in respect of voltage-resistance and permissible patient discharge currents

Test set-up:

Testing in respect of patient discharge currents was carried out in accordance with the requirements of the norm, with the aid of the diagrams 20 and 21 in the above mentioned norm. A network was used for measuring the discharge current as per diagram 15.

This network was connected in series with the sensor wrapped in metal foil, as prescribed in the norm.

For the event of the error 'Voltage on the application part', a voltage source with 253 V was additionally operated on the application part.

2.1 Voltage resistance

DIN EN 60601-1 /March 1996/ para.20

Medical electrical devices

Part 1: General restrictions for safety.

The sensors were ranked by CF as application part. As such they are subject to additional regulations in respect of voltage-resistance.

For performing the tests, the sensors were wrapped in metal foil. The high-voltage of 1.5 kV was applied between the connected up sensors connectors and the aluminum foil.. The applied voltage was continuously raised to the maximum level, at which it remained for 1 minute before being continuously reduced.

It was observed in the course of this the current flow as well as the voltage, in order to identify any possible incidences of voltage penetration.

2.3 Strike and creep distances

DIN EN 60601-1 /March 1996/ para. 57.10

Medical electrical devices

Part 1: General restrictions for safety.

The strike and creep distances were assessed through observation.

The requirements were 4 mm for the creep distances and 2.5 mm for the strike distances.

3. Test specification

3.1 Device configuration

Description:	Model:	Part/N:	max. discharge current in μ A for all switch combinations appl.part / 253 V on after earth / appl.part > 10 μ A / > 50 μ A	Voltage resistance 1500 V Insulation type B-d	Strike and creep distances > 2.5 / 4 mm
Test item:					
finger probe with extension cable	for Nellcor N180 SN:20856091 with (1)	P 856RA P 956E8	0,5 / 3,7	ok	ok
finger probe	for Ohmeda Type Biox 3700 SN:118-72170 with (1)	P 867RA	0,8 / 3,5	ok	ok
finger probe with extension cable	for Datex Type Satlite trans SN:404231 with (2)	P 873RA P 973E10	1,2 / 2,0	ok	ok
finger probe	for MSI SN:170276621 with (2)	P 861RA	Internal power supply only Testing not necessary	ok	ok
finger probe	for Datex Type Satlite trans SN:404231 with (2)	P 872RA	0,9 / 2,7	ok	ok
finger probe with extension cable	for Nellcor N180 SN:20856091 with (2)	P 858RA P 956E4	0,5 / 3,9	ok	ok
finger probe with adapter cable	for Novamatrix Type 575 SN:661065A with (1)	P 875RA	2,2 / 5,2	ok	ok
finger probe	for Novamatrix Type 575 SN:661065A with (1)	P 876RA	2,2 / 4,9	ok	ok
finger probe	for Datscope Type Accusat SN:11359H4 with (2)	P 863RA	1,9 / 4,5	ok	ok
finger probe with extension cable	for Datscope Type Accusat SN:11359H4 with (2)	P 864RA P 963E10	1,9 / 4,4	ok	ok
ok: Test passed e: Test not passed					

3.2 Operating conditions for the test item

Normal operation (ON) :

The operating status of the sensors represented their normal area of application both before and after the test. Pulse and blood-oxygen content were measured directly.

- Monitoring pulse and blood-oxygen content

Power supply:

230 V (+6 % / -10 %), 50 Hz
or battery pack

Climatic conditions for the tests:

Ambient temperature:	15 °C to 35 °C
Relative humidity:	10 % to 75 %
Air pressure	86 kPa to 106 kPa (860 mbar to 1060 mbar)

Humidity advance treatment:

The tests in respect of patient discharge current and voltage resistance were carried out after prior humidity treatment in accordance with section 4.10 DIN EN 60601-1 .

3.6 Criteria for interference characteristics

The assessment criteria outlined in the relevant standard are applicable.

Additional specification (non-approved function impairment):

The pulsoximeter's indicator must not display any inadmissible or illogical values.

No incidence of spark-over or disruptive voltage may occur during voltage resistance testing.

3.7 Information on sampling

The sensors were selected in such a way that an example of each length of a sensor type was checked, taking account of the extension cable.

5. Information on the measuring and testing equipment used

Description	Model/Type	Manufacturer	Serial no.	Last calibrat.	Meas./Test Procedure
Interference transmission					
Radio interference receiver	ESHS-10	R&S	842884/013	06.96	EC
Radio interference receiver	ESVS-10	R&S	843207/008	12.97	ER, EP
Two-core-V-mains model	ESH3-Z5	R&S	843012/025	06.96	EC
Two-core mains model 25 A	NNB 12	MEB	03619	--,--	EC
Contact head (active)	ESH2-Z2	R&S	843837/010	07.96	EC
Biconic antenna	HK116	R&S	842938/005	06.96	ER
log.-per. antennae	HL 223	R&S	843338/004	06.96	ER
Absorption transducer rod	MDS21	R&S	842291/020	07.96	EP
Mains model for EN 61000-3-2/3	NI	ZES	2415	04.97	MC1, MC2
Voltage source 16 kVA	5001 i	CI	HK 52257	04.97	MC1, MC2
Power analyzer	PM 3000 A	VOL	5370	04.97	MC1, MC2
Interference resistance					
Transience generator	TRA 1000	EMC	TRA10001-74	12.96	ID
ESD discharge circuit with pistols	TRA1Z02B	EMC	--	09.97	ID
Capacitive coupling regulator	ESD 101-66	EMC	--	10.95	ICI4
Variac (external)	TRA1H03B	EMC		10.95	DIPS
Surge-coupling kit f. signal transmission.	TRA1Z10B	EMC	--	10.95	ICI3
Signal generator 9 kHz - 1040 MHz	SMY01	R&S	842483/030	08.96	IR, ICS
Transmission amplifier	75A250	AR	18681		
One-channel power meter	NRVS	R&S	843209/009	08.96	ICS
One-channel power meter	NRVS	R&S	843537/030	08.96	ICS
10-V-volume meas. head	URV5-Z2	R&S	842558/075	08.96	ICS
100-V- volume meas. head	URV5-Z4	R&S	842619	08.96	ICS
Coupling rod / decoupling rod	203i / 203i-DCN	FCC	168 / 71	08.96	ICS
CDN, 1 Lead, 16 A	KEN-M1	MEB	12059	09.97	ICS
CDN, 2 Lead, 16 A	FCC-801-M2-16AMP	FCC	86	12.97	ICS
CDN, 3 Lead, 16 A	FCC-801-M3-16AMP	FCC	175	12.97	ICS
CDN, 1 Lead, coaxiale leads	FCC-801-C1	FCC	73	12.97	ICS
CDN, 4 lead, shielded signal lead	FCC-801-S4	FCC	19	12.97	ICS
CDN, 4 Lead, symmetr. signal lead	FCC-801-T4	FCC	74	12.97	ICS
Further measuring technology					
Short field probe set (E-, H-field)	HZ-11	R&S	843598/009	06.96	
Spectrum analyzer	U4941	ADV	3314F0002	08.96	
Spectrum analyzer	R4131D	ADV	024413	04.96	
Various accessories					

Key:

Manufacturer:

R&S	Rohde & Schwarz	EMC	EMC Partner Zürich	ZES	Zimmer Elektronik Systeme
CI	California Instruments	AR	Amplifier Research	VOL	Voltech
ADV	ADVANTEST	FCC	Fischer Custom Communications Inc.	MEB	Messelektronik Berlin

Measuring / test procedures:

EC	Radio interference voltage	9/150 kHz - 30 MHz
ER	Strength of radio interference field E-field	30 MHz - 1 GHz
EP	Radio interference power	30 MHz - 300 MHz
MC1	Mains transfers overshoots	
MC2	Mains transfers flicker	
ID	Interference resistance in respect of electrostatic discharge	
IR	Interference resistance in respect of high-frequency electromagnetic fields	

ICI3	Interference resistance in respect of rapid transience (burst)
ICI4	Interference resistance in respect of surge voltages and currents
ICS	Interference resistance in respect of high-frequency in-fed voltages and currents
DIPS	Interference resistance in respect of changes and interruptions of voltage