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Test report #498ENV11

EMV-Tests on the devices/equipment:

Sensors for pulsoximeters

Test item:

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

Distributor:

EnviteC Wismar GmbH
Philipp-Müller-Straße 12
23966 Wismar

Testing laboratory:

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

Test specification:

Interference resistance:	Electrostatic discharge	
	High-frequency electromagentic field	DIN EN 60601-1-2 /09.94/

Test period: **19./20. January 1998**

This test report contains **10** 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.

1. General information on the test item(s)

Description:	sensors for pulsoxymeters
Model:	Sensors for the device from Nellcor, Ohmeda, Datex, MCI, Novametrix 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, Novametrix 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.

System frequencies:	--

Advance measures on EMC: --

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 test

2.1 Interference resistance

DIN EN 60601-1-2 /September 1994/
Medical electrical devices
2. Supplementary standard: Electromagnetic compatiblity (EMC)-Regulations and tests

Interference resistance:	Electrostatic discharge	DIN EN 60601-1-2 / 09.94
	High-frequency electromagnetic field	DIN EN 60601-1-2 / 09.94

3. Test specification

3.1 Device configuration

Description:	Model:	Part no.:	Distributor:	Length:
Test item:				
finger probe with extension cable	for Nellcor N180 SN:20856091 with (1)	P 856RA P 956E8	Envitec	90 cm 2,35 m
finger probe	for Ohmeda type Biox 3700 SN:118-72170 with (1)	P 867RA	Envitec	3,60 cm
finger probe with extension cable	for Datex type Satlite trans SN:404231 with (2)	P 873RA P 973E10	Envitec	90 cm 2,35 m
finger probe	for MSI SN:170276621 with (2)	P 861RA	Envitec	100 cm
finger probe	for Datex type Satlite trans SN:404231 with (2)	P 872RA	Envitec	4,00 m
finger probe with extension cable	for Nellcor N180 SN:20856091 with (2)	P 858RA P 956E4	Envitec	3,10 m 1,00 m
finger probe with adapter cable	for Novametrix type 575 SN:661065A with (1)	P 875RA	Envitec	310 cm 20 cm
finger probe	for Novametrix type 575 SN:661065A with (1)	P 876RA	Envitec	310 cm
finger probe	for Datscope type Accusat SN:11359H4 with (2)	P 863RA	Envitec	3,60 m
finger probe with extension cable	for Datscope type Accusat SN:11359H4 with (2)	P 864RA P 963E10	Envitec	1,10 m 2,40 m

Simulators used:

(1) Simulator „Index 2" from Biotek

(2) SpO2 -Simulator DL3000 (SN: 6,181,297)

3.4 Operating conditions for the test item

Normal operation (ON) :

The status of the test item during the test represented its normal area of application. The pulse and blood-oxygen content were measured directly.

- Monitoring pulse and blood-oxygen content

Power supply:

230 V (+6 % / -10 %), 50 Hz
or by means of internal power supply (battery pack)

Climatic conditions for the test:

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

3. 5 Simulation of operating status

The measurements took place with the simulators specified in the device configuration.

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.

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.

4. Measuring and test results

4.1 Information on measuring uncertainty and tolerances

The information on measuring uncertainty is found in section 5.

4.2 Interference resistance tests

4.2.0 Criteria for interference characteristics during the interference resistance tests

Assessment criteria according to Technical Basic Standard:

Assessment criteria A:
The equipment must continue to operate as prescribed. There must be no impairment to its operating characteristics nor failure of its function below those limits set by the manufacturer for minimum operational quality, whilst the equipment is being operated in accordance with specifications. In certain cases the minimum operating quality may be substituted by an admissible reduction in operational quality. If the minimum operating quality or admissible reduction in operational quality is not specified by the manufacturer, each of these factors may be determined from the product description and documentation, and from that which the users might reasonably expect from such equipment under normal use.

Assessment criteria B:
The equipment must continue to operate as prescribed. There must be no impairment to its operating characteristics nor failure of its function below those limits set by the manufacturer for minimum operational quality, whilst the equipment is being operated in accordance with specifications. In certain cases the minimum operating quality may be substituted by an admissible reduction in operational quality. However, a reduction in operational characteristics is permissible during the test. A change of the type of operation set or loss of stored data is however not allowed. If the minimum operating quality or admissible reduction in operational quality is not specified by the manufacturer, each of these factors may be determined from the product description and documentation, and from that which the users might reasonably expect from such equipment under normal use.

Assessment criteria C:
A temporary interruption of function is permitted, if the function reinstates itself or the function can be reinstated by means of the settings/operating element.

In addition to this, the criteria in section 3. 6 have, in agreement with the manufacturer (applicant), been defined as inadmissible function impairments

4.2.1 Electrostatic discharge (ESD)

Representative operating conditions:
Monitoring pulse and blood-oxygen content

Criteria for interference characteristics:
Assessment criteria B

Test set-up:
The test is set up in accordance with EN 61000-4-2.

Information on performance of the tests:
At each test position, a minimum of 20 discharges took place for each polarity. In the course of this the test item and the measuring values were observed for occurrences of deviation from normal characteristics.

Tests:

Operating conditions/version:	Position of discharge	Test procedure:	Test definition:	Polarity	No./repetit. discharges:
Monitoring pulse and blood-oxygen content	entire sensor	D,L	8 kV	pos./neg.	min. 20
Monitoring pulse and blood-oxygen content.	metal clip	D,K	4 kV	pos./neg.	min. 20

Key:

D	direct discharge onto the test item
I	indirect discharge onto the test item
K	contact discharge
L	air discharge
H	horizontal coupling plate under the test item

Evaluation of the test results/certification status:

During this EMC test, no relevant function impairment could be determined. The interference characteristics criteria were met. There was no function failure nor loss of data, neither was there any change in the type of operation set.

The test item specified in section 3 fulfills the requirements for interference resistance in respect of electrostatic discharge as per

4.2.2 Interference resistance in respect of high-frequency electromagnetic fields

Representative operating conditions:
Monitoring pulse and blood-oxygen content

Criteria for interference characteristics:
Assessment criteria A

Test set-up:
The test is set up according to standard requirement. The test item was placed 0.8 m above a reference earth surface.

Information on the performance of the test:
The frequency range was passed through step-wise. Each step represented 1% of the base frequency and subsequently 1 % of the previous frequency level.
Standing time per step, depending on the reaction time of the test item: 1 sec.
Frequency range: 27 MHz - 1000 MHz
Modulation: 80 % AM

Test definition level: 3 V/m

The test item was exposed to the field from the front with both horizontal and vertical polarization.

Evaluation of the test results/certification status::

During this EMC test, no relevant function impairment could be determined. The interference characteristics criteria were met. There was no function failure nor loss of data, neither was there any change in the type of operation set.

The test item specified in section 3 fulfils, according to the test set-up requirements for interference resistance in respect of high-frequency electromagnetic fields as per

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 applifier	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, 4 Lead, unshielded signal lead	FCC-801-AF4	FCC	51	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 transferes 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 to voltage