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**Test report #498ENV11****EMV-Tests 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:**

|                                 |                                      |                          |
|---------------------------------|--------------------------------------|--------------------------|
| <b>Interference resistance:</b> | Electrostatic discharge              |                          |
|                                 | High-frequency electromagnetic 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.

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## 1. General information on the test item(s)

|                        |   |
|------------------------|---|
| <b>Description:</b>    | sensors for pulsoxymeters   |
| <b>Model:</b>          | Sensors for the device from Nellcor, Ohmeda, Datex, MCI, Novamatrix and Datascope |
| <b>Serial number:</b>  | as per type table   |
| <b>Distributor:</b>    | EnviteC Wismar GmbH   |
| <b>Contact person:</b> | 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.

|                            |    |
|----------------------------|----|
| <b>System frequencies:</b> | -- |
|----------------------------|----|

**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 compatibility (EMC)-Regulations and tests

|                                 |                                      |                          |
|---------------------------------|--------------------------------------|--------------------------|
| <b>Interference resistance:</b> | 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:          |
|---|--|---------------------|--------------|------------------|
| <b>Test item:</b>                                 |  |                     |              |                  |
| finger probe with extension cable                 | for Nellcor N180<br>SN:20856091<br>with (1)              | P 856RA<br>P 956E8  | Envitec      | 90 cm<br>2,35 m  |
| finger probe                                      | for Ohmeda<br>type Biox 3700<br>SN:118-72170<br>with (1) | P 867RA             | Envitec      | 3,60 cm          |
| finger probe with extension cable                 | for Datex<br>type Satlite trans<br>SN:404231<br>with (2) | P 873RA<br>P 973E10 | Envitec      | 90 cm<br>2,35 m  |
| finger probe                                      | for MSI<br>SN:170276621<br>with (2)                      | P 861RA             | Envitec      | 100 cm           |
| finger probe                                      | for Datex<br>type Satlite trans<br>SN:404231<br>with (2) | P 872RA             | Envitec      | 4,00 m           |
| finger probe with extension cable                 | for Nellcor N180<br>SN:20856091<br>with (2)              | P 858RA<br>P 956E4  | Envitec      | 3,10 m<br>1,00 m |
| finger probe with adapter cable                   | for Novametrix<br>type 575<br>SN:661065A<br>with (1)     | P 875RA             | Envitec      | 310 cm<br>20 cm  |
| finger probe                                      | for Novametrix<br>type 575<br>SN:661065A<br>with (1)     | P 876RA             | Envitec      | 310 cm           |
| finger probe                                      | for Datscope<br>type Accusat<br>SN:11359H4<br>with (2)   | P 863RA             | Envitec      | 3,60 m           |
| finger probe with extension cable                 | for Datscope<br>type Accusat<br>SN:11359H4<br>with (2)   | P 864RA<br>P 963E10 | Envitec      | 1,10 m<br>2,40 m |
| <b>Simulators used:</b>                           |  |                     |              |                  |
| <b>(1) Simulator „Index 2“ from Biotek</b>        |  |                     |              |                  |
| <b>(2) SpO2 -Simulator DL3000 (SN: 6,181,297)</b> |  |                     |              |                  |

### 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                                 |
| TT | 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 fulfills, according to the test results, the 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 |
|--|------------------|--------------|-------------|----------------|----------------------|
| <b>Interference transmission</b>           |                  |              |             |                |                      |
| 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             |
| <b>Interference resistance</b>             |                  |              |             |                |                      |
| 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                  |
| <b>Further measuring technology</b>        |                  |              |             |                |                      |
| 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        |

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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:**

|                       |                                      |                        |
|-----------------------|--------------------------------------|------------------------|
| <b>Device safety:</b> | 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)

|                        |  |
|------------------------|--|
| <b>Description:</b>    | Sesors for pulsoximeters   |
| <b>Model:</b>          | Sensors for the devices from Nellcor, Ohmeda, Datex, MCI, Novamatrix and Datascope |
| <b>Serial number:</b>  | as per type table  |
| <b>Distributor:</b>    | EnviteC Wismar GmbH  |
| <b>Contact person:</b> | 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 $\mu$ A<br>for all switch combinations<br>appl.part / 253 V on<br>after earth / appl.part<br>> 10 $\mu$ A / > 50 $\mu$ A | Voltage resistance<br>1500 V<br>Insulation type B-d | Strike and creep<br>distances<br>> 2.5 / 4 mm |
|---|---|---------------------|--|---|---|
| <b>Test item:</b>                                   |   |                     |  |   |   |
| finger probe with<br>extension cable                | for Nellcor<br>N180<br>SN:20856091<br>with (1)              | P 856RA<br>P 956E8  | 0,5 / 3,7  | ok  | ok  |
| finger probe  | for Ohmeda<br>Type Biox 3700<br>SN:118-72170<br>with (1)    | P 867RA             | 0,8 / 3,5  | ok  | ok  |
| finger probe with<br>extension cable                | for Datex<br>Type Satlite<br>trans<br>SN:404231<br>with (2) | P 873RA<br>P 973E10 | 1,2 / 2,0  | ok  | ok  |
| finger probe  | for MSI<br>SN:170276621<br>with (2)                         | P 861RA             | Internal power supply<br>only<br>Testing not necessary   | ok  | ok  |
| finger probe  | for Datex<br>Type Satlite<br>trans<br>SN:404231<br>with (2) | P 872RA             | 0,9 / 2,7  | ok  | ok  |
| finger probe with<br>extension cable                | for Nellcor<br>N180<br>SN:20856091<br>with (2)              | P 858RA<br>P 956E4  | 0,5 / 3,9  | ok  | ok  |
| finger probe with<br>adapter cable                  | for Novamatrix<br>Type 575<br>SN:661065A<br>with (1)        | P 875RA             | 2,2 / 5,2  | ok  | ok  |
| finger probe  | for Novamatrix<br>Type 575<br>SN:661065A<br>with (1)        | P 876RA             | 2,2 / 4,9  | ok  | ok  |
| finger probe  | for Datscope<br>Type Accusat<br>SN:11359H4<br>with (2)      | P 863RA             | 1,9 / 4,5  | ok  | ok  |
| finger probe<br>with extension cable                | for Datscope<br>Type Accusat<br>SN:11359H4<br>with (2)      | P 864RA<br>P 963E10 | 1,9 / 4,4  | ok  | ok  |
| <b>ok: Test passed</b><br><b>e: Test not passed</b> |   |                     |  |   |   |

### 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 |
|--|------------------|--------------|-------------|----------------|----------------------|
| <b>Interference transmission</b>           |                  |              |             |                |                      |
| 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             |
| <b>Interference resistance</b>             |                  |              |             |                |                      |
| 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                  |
| <b>Further measuring technology</b>        |                  |              |             |                |                      |
| 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        |

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Wismar, 5. Juli 1998

**EMC-Tests on the devices/equipment:*****SpO2 Sensor*****Test item:**

**Description:** SpO2 Sensor  
**Model:** Finger probe  
**Serial number:** P856 RA

**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:**

|                               |  |                                 |
|-------------------------------|--|---------------------------------|
| <b>Interference discharge</b> | <b>Strength of radio interference field<br/>(comparison with Nellcor Sensor DS 100A)</b> | <b>DIN EN 60601-1-2 /09.94/</b> |
|-------------------------------|--|---------------------------------|

**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 generalisations 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:** SpO2 sensor  
**Model:** Finer probe  
**Serial number:** P856 RA  
**Distributor:** EnviteC Wismar GmbH  
**Contact person:** Herr Scholl

**Brief description:** This sensor is an accessory for Nellcor pulsoximeters.

**System frequencies:** none

**Advance measures on EMC:** none

**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 discharge

**DIN EN 55011 (DIN VDE 0875-11/October 1997/**

**Radio interference of electrical devices and equipment:**

**Thresholds and measuring processes for radio interference of industrial, scientific and medical high-frequency devices (ISM devices).**

The term ISM covers devices or equipment which is developed for the generation and/or local consumption of high-frequency energy for industrial, scientific, medical, domestic or similar purposes.

| Testing method   | Reference norm / client specified |
|--|-----------------------------------|
| Strength of radio interference field in frequency range 30 MHz - 1 GHz | DIN EN 60601-1-2 /09.94/          |

## 3. Measuring and test results

### 3.1 Preface and classification

The test item must meet the requirements of CISPR 11

#### Classification

The device is classified as an industrial, scientific and medical high-frequency device. As such, sub-classification into classes and groups is necessary.

#### Group sub-classification

*Group 1 ISM devices: Group 1 contains all ISM devices in which circuit-bound HF-energy, which itself is necessary for the internal function of the device, is purposely generated.*

*Group 2 ISM devices: Group 2 contains all ISM devices in which HF-energy is generated purposely as electromagnetic radiation for the treatment of materials, and EDM (electrical discharge machining).*

#### Class sub-classification

*Devices in class A are devices which are suitable for use in all other areas apart from residential and in such equipment directly connected to a mains power supply which (also) supplies power to residential property.*

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*Devices in class B are devices which are suitable for use in residential areas and in such equipment which is directly connected to a mains power supply which (also) supplies power to residential property.*

Accordingly the device is classified as follows:

Device group 1, class B

### 3.2 Interference discharge

#### 3.2.1 Strength of radio interference field (30 MHz - 1 GHz)

Base norm:

DIN EN 55011 / 10.97 /

Representative operating conditions:

(no info!)

Measuring set-up:

- Test set-up from beginning

Measuring process:

The strength of the radio interference field was determined at its maximum in the entire frequency range. In the course of this the positions of the test item and the antenna were changed.

At the start a pre-scan was carried out with an antenna height of 1.5 m and horizontal polarisation.

The comparison revealed no differences in the radiation characteristics of the two sensors.

Frequency range/Threshold class:

In accordance with the norm the strength of the radio interference field in the frequency range of 30 MHz to 1 GHz was determined. The test item was classified as threshold class B, since the area of application is specified as both residential and industrial areas.

Evaluation of the measuring results/certification status:

During this EMC test, no relevant interference emissions from the test item were found. Measuring was carried out in a shielded, absorber-lined cabin and in the open.