



**TEST REPORT CONCERNING THE COMPLIANCE OF  
A MEDIKZAP, BRAND MEDI-FLOWERY APS, MODEL  
TA, IN ACCORDANCE WITH THE STANDARD: EN  
60601-1-2: 2007**

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Industry Canada : IC3501  
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### Description of test item

Test item : MEDIKZAP  
Manufacturer : Medi-Flowery ApS  
Brand : Medi-Flowery ApS  
Model/Version : TA  
Revision : -  
Receipt date : 05-03-2008

### Applicant information

Applicant's representative : Mr. J. Elmborg  
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### Test(s) performed

Location : Niekerk  
Test(s) started : July 25, 2008  
Test(s) completed : August 4, 2008  
Purpose of tests : Compliance with standards  
Test specification(s) : EN 60601-1-2:2007

Project leader : T.E.T. Koning

Test engineer : A.J.K. Hut

Report written by : A.J.K. Hut

Report approved by : H.J. Pieters

Report date : August 7, 2008

This report is in conformity with NEN-EN-ISO/IEC 17025: 2005.

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# 1 General.

## 1.1 Applied standards.

The MEDIKZAP, brand Medi-Flowery ApS, model TA, has been tested in accordance with the standards EN 60601-1-2 2007 (emission and immunity).

## 1.2 Detailed description of test configuration, input and output ports.

The MEDIKZAP brand Medi-Flowery ApS, model TA, used for medical treatment in the configuration as described below, will be referred to as EUT for the purpose of this test report.

### 1.2.1 Description of test configuration.

Test item 1 : MEDIKZAP  
 Manufacturer : Medi-Flowery ApS  
 Brand : Medi-Flowery ApS  
 Model/partnumber : TA  
 Type :  
 Serial number : 38b60000001PT  
 Voltage input rating : battery 2 x 1,5V penlight AA.  
 Remarks : ---

### 1.2.2 Description of tested input and output ports.

Number	Terminal	From	To	Remarks
1	output	EUT	Metal bals	<3 m

Table 1





## 2 Emission.


The EUT has been tested in conformity with (parts) the standard EN 61601-1-2: 2007 and all relevant amendments (conducted and radiated field strength measurements concerning the emission of radiated and conducted electromagnetic disturbances).



## 2.1 AC mains power input ports.

The disturbance voltage levels at the AC mains power input port of the EUT to be measured in conformity with- and according to the criteria as stated below.

Basic standard	:	EN 60601-1-2: 2007
Test set-up	:	EN 55011: 1998 and all relevant amendments
Frequency range 1	:	0.15 MHz – 0.5 MHz
Limit	:	66.0 – 56.0dB(μV) quasi peak, 56.0 – 46.0 dB(μV) average
Frequency range 2	:	0.5 – 5.0 MHz
Limit	:	56.0 dB(μV) quasi peak, 46.0 dB(μV) average
Frequency range 3	:	5.0 - 30 MHz
Limit	:	60.0 dB(μV) quasi peak, 50.0 dB(μV) average


Result of the measurements concerning the emission of disturbance voltage levels at the AC mains input port of the EUT	<del>PASS / FAIL</del> / NOT APPLICABLE
Name of test engineer:	A.J.K. Hut
Signature:	
Date:	August 7, 2008
REMARK: <b>EUT has no AC input ports.</b>	

## 2.2 Enclosure.

The radiated field strength levels (electric component) have been measured in conformity with- and according to the criteria as stated below. Tested in mode 1.

Basic standard	:	EN 60601-1-2:2007
Test set-up	:	EN55011:1998 and all relevant amendments
Measuring distance	:	10 meters
Frequency range 1	:	30 MHz - 230 MHz
Limits	:	30 dB( $\mu$ V/m)
Frequency range 2	:	230 MHz - 1000 MHz
Limits	:	37 dB( $\mu$ V/m)

Detailed results of the measurements concerning radiated field strength levels (electric component), emitted by the EUT, are depicted in table 4 on the next page of this test report.

Result of the measurements concerning radiated electromagnetic fields (electric component) emitted by the EUT (enclosure)	<b>PASS / FAIL / NOT APPLICABLE</b>
Name of test engineer:	A.J.K. Hut
Signature:	
Date:	August 7, 2008
<b>REMARKS:</b>	
None.	

### Utilized test equipment:

Inventory number	Description	Brand	Type
12636	Plastic measurement room	Polyforce	-
13886	Open Area Test Site	Comtest	-
14277	Antenna mast 4.7m	Shoshin	AP-4702C
14278	Controller OATS	Comtest	4630-100
15633	Biconilog antenna 30MHz – 1000MHz	Chase	CBL6111B
15667	EMI test receiver 9kHz – 2750MHz	Rohde & Schwarz	ESCS 30
99108	Turntable OATS	Heinrich Deisel	HD050
99608	Controller antenna mast	EMCS	DOC-202
12526	Field site source	EMCO	Model 4610
99071	Coax cable	Intercond	RG213
99069	Coax cable	Intercond	RG213
99070	Coax cable	Intercond	RG213





Frequency (MHz)	Measurement results dB( $\mu$ V)/m @ 10 meters Quasi-peak		Limits dB( $\mu$ V)/m @ 10 meters Quasi-peak (Class B)	Result
	Vertical	Horizontal		
30.0-230.0	<23.0	<26.0	30.0	PASS
230.0-1000.0	<25.0	<25.0	37.0	PASS


Table 4

The results of the measurements, carried out in conformity with the standard EN 55011:1998 including all relevant amendments, concerning radiated field strength levels (electric component), emitted by the EUT in the configuration and operation mode(s) as stated in this test report, are depicted in table 4.

### 2.3 Harmonic current emissions.

The emission of harmonic currents at the AC mains connection terminals of the EUT to be measured in conformity with- and according to the criteria as stated below.

Basic standard : EN 61000-3-2: 2006  
 Test set-up : EN 61000-3-2: 2006  
 Frequency range : 100 Hz - 2000 Hz


Result of the measurements concerning the emission of harmonic currents at the AC mains connection terminals of the EUT.	<b><del>PASS / FAIL</del> / NOT APPLICABLE</b>
Name of test engineer:  Signature:  Date:	A.J.K Hut    August 7, 2008
REMARKS:  <b>EUT has no AC input power ports.</b>	



## 2.4 Voltage fluctuations and flicker.

Voltage fluctuations and flicker at the AC mains connection terminals of the EUT to be measured in conformity with- and according to the criteria as stated below.

Basic standard : EN 61000-3-3: 1995, Amd A1:2001 and Amd A2:2005  
Test set-up : EN 61000-3-3: 1995, Amd A1:2001 and Amd A2:2005

Result of the measurements concerning voltage fluctuations and flicker at the AC mains connection terminals of the EUT.	<del>PASS / FAIL</del> NOT APPLICABLE
Name of test engineer:	A.J.K. Hut
Signature:	
Date:	August 7, 2008
REMARKS:  <b>EUT has no AC input power ports.</b>	

## 3 Immunity.

The EUT has been tested in conformity with parts of the standard EN 60601-1-2: 2007 (immunity) concerning the susceptibility to continuous and transient, conducted and radiated disturbances including electrostatic discharges.

### 3.1 Performance criteria.

The general principles (performance criteria) for the evaluation of the immunity test results are given below. The details are in EN 60601-1-2:2007

#### 3.1.1 Not allowed performance degradation.

The following DEGRADATIONS associated with ESSENTIAL PERFORMANCE and safety shall not be allowed:


- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- false alarms;
- cessation or interruption of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise is indistinguishable from physiologically produced signals or the noise interferes with interpretation of physiologically-produced signals;
- artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm.

## 3.2 Enclosure port.

### 3.2.1 Radio-frequency electromagnetic field. Amplitude modulated.

The susceptibility of the EUT to radio-frequency electromagnetic fields has been tested in conformity with-and according to the criteria as stated below. Tested in mode 1.

Basic standard	:	EN 60601-1-2: 2007
Test set-up	:	EN 61000-4-3: 2006
Frequency range	:	80 MHz - 2500 MHz
Field strength level	:	3 V <sub>rms</sub> /m (selected without modulation, applied with modulation)
Modulation	:	1 kHz, modulation depth 80%
Performance criterion	:	Par. 3.3.1

Result of the tests concerning the susceptibility of the EUT to radio-frequency electromagnetic fields (amplitude modulated, enclosure port)	<b>PASS / <del>FAIL</del> / NOT APPLICABLE</b>
Name of test engineer:	T.E.T. Koning
Signature:	
Date:	July 25, 2008
REMARKS:	
<b>Before, during and after the tests no loss of performance.</b>	

### Utilized test equipment:

Inventory number	Description	Brand	Type
12441	Tripod	EMCO	TR3
80012	Signalgenerator 250kHz-4GHz	Agilent	E4422B
14051	Compact anechoic room	Euroshield/ Comtest	RFSD-F-100
14298	Amplifier 0.01 MHz-220 MHz	SPS/Comtech	SPS7010
14307	Amplifier 200 MHz-1000 MHz	SPS/Comtech	SPS8030
13826	Amplifier 1-2GHz 30W	Milmega	AS0102
80005	Amplifier 2-4GHz 15W	Milmega	AS0204
14351	Biconilog antenna 20 MHz-1100 MHz	EMCO	3143
15392	Signalgenerator 0.1 MHz-2048 MHz	Rohde & Schwarz	SMY02
99107	Turntable anechoic room + controller	Heinrich Deisel	HD050
99109	Color television	Erres	S G290AE
99110	Camera	Sanyo	EX220P
12483	Guide horn antenna 1-18GHz	EMCO	Model3115
80000+80001	Isotropic electric field probe 0,5-6GHz	Holaday	HJ4433GRE
15232	Oscilloscope 100MHz 1GS/s	Tektronix	TDS220

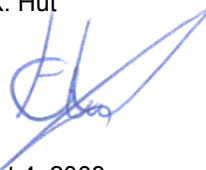


Photo 3. Set-up RF Radiated Immunity

### 3.2.2 Electrostatic discharge.

The susceptibility of the EUT to electrostatic discharges has been tested in conformity with- and according to the criteria as stated below. Tested in mode 1.

Basic standard : EN 60601-1-2:2007  
 Test set-up : EN 61000-4-2: 2001  
 Test levels : ±4 kV and ±8 kV air discharge  
                   : ±2 kV and ±4 kV contact discharge  
 Performance criterion : Par. 3.3.1

Result of the tests concerning the susceptibility of the EUT to electrostatic discharges (enclosure port)	<b>PASS / <del>FAIL</del> / NOT APPLICABLE</b>
Name of test engineer:	A.J.K. Hut
Signature:	
Date:	August 4, 2008
REMARKS:  <b>During and after the tests no loss of performance.</b>	

#### Utilized test equipment:

Inventory number	Description	Brand	Type
99002	ESD simulator system	Schaffner	NSG 435-01
99660+99661	Resistor 470K	Philips	-
99604	ESD validation unit	TUV	-


## Signal ports including telecommunication ports.

### 3.2.3 Radio-frequency (common mode). Amplitude modulated.

The susceptibility of the EUT to radio-frequency (common mode)<sup>1)</sup>, amplitude modulated, to be tested in conformity with- and according to the criteria as stated below.

Basic standard : EN 60601-1-2:2007  
 Test set-up : EN 61000-4-6: 2007  
 Frequency range : 0.15 MHz - 80 MHz  
 Test level : 3 V<sub>rms</sub> (selected without modulation, applied with modulation)  
 Modulation : 1 kHz, modulation depth 80%  
 Source impedance : 150 Ohms  
 Performance criterion : A

Note<sup>1)</sup> : Conducted only on ports interfacing with cables whose total length, according to the manufacturer's functional specification, may exceed 3 meters

Result of the tests concerning the susceptibility of the EUT to radio-frequency (common mode, amplitude modulated, ports for signal lines including telecommunication ports)	<del>PASS / FAIL</del> NOT APPLICABLE
Name of test engineer:  Signature:  Date:	T.E.T. Koning    August 7, 2008
REMARKS:  <b>EUT has no telecommunication ports</b>	




### 3.2.4 Fast transients.

The susceptibility of the EUT to fast transients has been tested in conformity with- and according to the criteria as stated below.

Basic standard : EN 60601-1-2:2007  
 Test set-up : EN 61000-4-4:2005  
 Test level :  $\pm 2$  kV  
 Tr/Th : 5/50 ns  
 Repetition frequency : 5 kHz  
 Performance criterion : Par. 3.3.1

Note<sup>1)</sup> : Conducted only on ports interfacing with cables whose total length, according to the manufacturer's functional specification, may exceed 3 meters


Result of the tests concerning the susceptibility of the EUT to fast transients	<b><del>PASS / FAIL</del> / NOT APPLICABLE</b>
Name of test engineer:  Signature:  Date:	T.E.T. Koning    August 8, 2008
REMARKS:  <b>EUT has no cables longer than 3 meters.</b>	

### 3.3 AC input and AC output power ports.

#### 3.3.1 Radio-frequency (common mode). Amplitude modulated.

The susceptibility of the EUT to radio-frequency (common mode), amplitude modulated, has been tested in conformity with- and according to the criteria as stated below.

Basic standard : EN 60601-1-2: 2007  
 Test set-up : EN 61000-4-6: 2007  
 Frequency range : 0.15 MHz - 80 MHz  
 Test level : 3 V<sub>rms</sub> (selected without modulation, applied with modulation)  
 Modulation : 1 kHz, modulation depth 80%  
 Source impedance : 150 Ohms  
 Performance criterion : Par. 3.3.1


Result of the tests concerning the susceptibility of the EUT to radio-frequency (common mode, amplitude modulated, AC input and AC output power ports)	<b><del>PASS / FAIL</del> / NOT APPLICABLE</b>
Name of test engineer:  Signature:  Date:	A.J.K. Hut    August 8, 2008
REMARKS:  <b>EUT has no AC input and output ports with cables longer than 3 meters.</b>	

### 3.3.2 Surges.

The susceptibility of the EUT to surges<sup>1)</sup> has been tested in conformity with- and according to the criteria as stated below.

Basic standard : EN 60601-1-2:2007  
 Test set-up : EN 61000-4-5:2007  
 Test level 1 : ±0.5 kV, ±1.0 kV  
 Test level 2 : ±2 kV  
 Tr/Th : 1.2/50 (8/20) µs  
 Number of pulses : 5  
 Performance criterion : Par. 3.3.1

Note<sup>1)</sup> : Applicable only to input ports


Result of the tests concerning the susceptibility of the EUT to surges (AC input and AC output power ports)	<b>PASS / FAIL / NOT APPLICABLE</b>
Name of test engineer:  Signature:  Date:	A.J.K. Hut    August 8, 2008
REMARKS:  <b>EUT works on batteries.</b>	



**3.3.3 Fast transients (common mode).**

The susceptibility of the EUT to fast transients (common mode) has been tested in conformity with- and according to the criteria as stated below.

Basic standard : EN 60601-1-2: 2007  
Test set-up : EN 61000-4-4: 2004  
Test level : ±1 kV  
Tr/Th : 5/50 ns  
Repetition frequency : 5 kHz  
Performance criterion : Par. 3.3.1


Result of the tests concerning the susceptibility of the EUT to fast transients (common mode, AC input and AC output power ports)	<b>PASS / FAIL / NOT APPLICABLE</b>
<p style="text-align: right;">Name of test engineer:</p> <p style="text-align: right;">Signature:</p> <p style="text-align: right;">Date:</p>	<p>A.J.K Hut</p>  <p>August 8, 2008</p>
<p>REMARKS:</p> <p><b>EUT has no cables longer than 3 meters and works on batteries.</b></p>	

**Voltage dips and interruptions.**

The susceptibility of the EUT to voltage dips and interruptions<sup>1)</sup> has been tested in conformity with- and according to the criteria as stated below.

Basic standard	:	EN 61610-1-2: 2007
Test set-up	:	EN 61000-4-11: 2004
Test level (a)	:	Reduction of the supply voltage of > 95% for 0.5 period <sup>2)</sup>
Performance criterion	:	Par. 3.3.1
Test level (b)	:	Reduction of the supply voltage of 60% for 5 periods <sup>2)</sup>
Performance criterion	:	Par. 3.3.1
Test level (c)	:	Reduction of the supply voltage of 30% for 25 periods <sup>2)</sup>
Performance criterion	:	Par. 3.3.1
Test level (c)	:	Reduction of the supply voltage of > 95% for 5000 ms
Performance criterion	:	Par. 3.3.1

Note<sup>1)</sup> : Applicable only to input ports  
 Note<sup>2)</sup> : Voltage shift at zero crossing

Result of the tests concerning the susceptibility of the EUT to voltage dips and interruptions (AC input and AC output power ports)	<b>PASS / FAIL / NOT APPLICABLE</b>
Name of test engineer:	A.J.K. Hut
Signature:	
Date:	August 8, 2008
REMARKS: <b>EUT works on batteries.</b>	



## 4 Conclusion.

The MEDIKZAP, brand Medi-Flowery ApS, model TA, complies with the standard EN 60601-1-2:2007 (emission and immunity) in the configuration and operation mode(s) as stated and tested in this test report.