

IEC 60601-1-2 Compliance

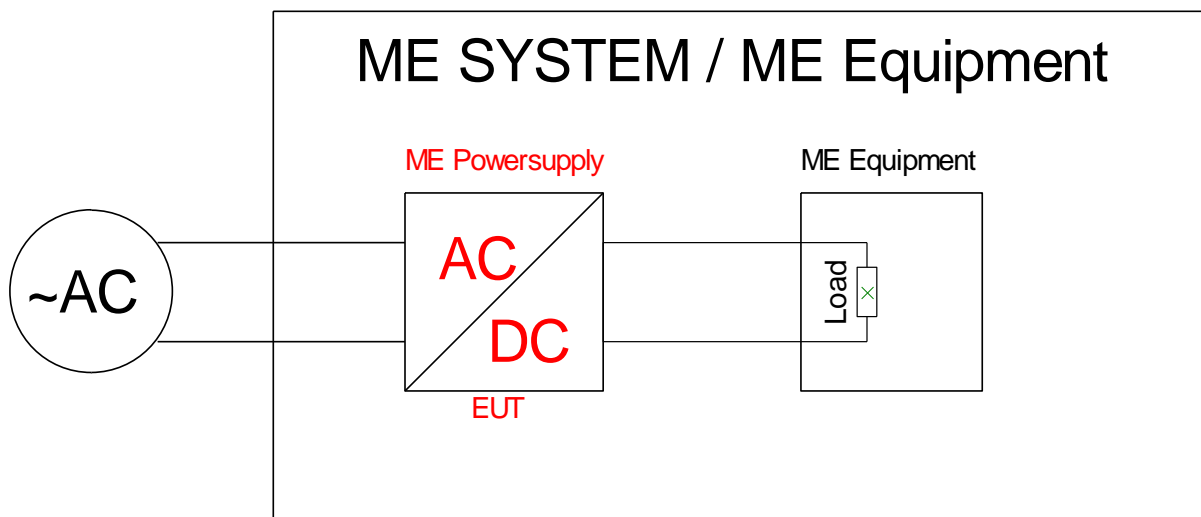
valid for the following models/model/families:

FW8002M (FOX6M), FW8000M (FOX12M), FW8001M (FOX18M), FW8030M (FOX30M), FW8030M/DT (FOX30-DM) FW8002M/USB (FOX6M-USB), FW8000M/USB (FOX12M-USB)

MANUFACTURER:

FRIWO Gerätebau GmbH
 Von-Liebig-Straße 11
 D-48346 Ostbevern
 Germany

APPLICATION:



BASIC SAFETY

The BASIC SAFETY is ensured, if it fulfills the safety requirements of the standard IEC 60601-1, especially the requirements against electric shock, mechanical hazards and hazards out of over temperatures.

ESSENTIAL PERFORMANCE

The PS has no direct clinical function or essential performance acc. to IEC60601-1.

INTENDED USE

The device was developed to supply a defined output voltage and output current according to the specifications, instructions and information provided by the MANUFACTURER.

Performance reduction is acc. to the following criteria allowed. This has to be considered in the risk analysis of the ME Equipment or ME System.

Criteria A

The device withstands the test without damage or other disturbances, during and after the test the device works inside the specified limitations correctly. The basic safety is ensured continuously

Criteria B

The device withstands the test without damage or other disturbances, after the test the device works inside the specified limitations correctly. The basic safety is ensured continuously.

Criteria C

A temporary malfunction is permitted, if the function itself restores or is recoverable by user intervention. The basic safety is ensured continuously

INTENDED ENVIRONMENTS

Intended environments are the typical professional healthcare facility (Clinic, hospital) environment and Home healthcare (medical practice and household) environment.

Technical Description

Technical details and information of the power supply are described in the specification and the instruction manual.

The power supply is tested and designed to fulfill the EMI behavior of the specified environment, it includes specific EMI filter to reduce the Emissions which are defined in the IEC60601-1-2 standard.

Please read and observe the complete technical documentation to avoid adverse events to the patient and operator.

STANDARD

IEC 60601-1-2 :2014 4th Edition (EN 60601-1-2 : 2015)

The above listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the above listed models should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The above listed models use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The above listed models are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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Enclosure Port

Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ± 2,4,8,15 kV Air	±8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Criteria B
Radiated RF EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM 1kHz	10 V/m 80 MHz – 2,7 GHz	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria A
	385MHz (18Hz Pulse Modulation)	27 V/m	
	450MHz (FM+/-5KHz deviation 1kHz sine or 18Hz Pulse Modulation)	28 V/m	
	710MHz (217Hz PM)	9 V/m	
	745MHz (217Hz PM)	9 V/m	
	780MHz (217Hz PM)	9 V/m	
	810MHz (18Hz PM)	28 V/m	
	870MHz (18Hz PM)	28 V/m	
	930MHz (18Hz PM)	28 V/m	
	1720MHz (217Hz PM)	28 V/m	
	1845MHz (217Hz PM)	28 V/m	
	1970MHz (217Hz PM)	28 V/m	
	2450MHz (217Hz PM)	28 V/m	
	5240MHz (217Hz PM)	9 V/m	
	5500MHz (217Hz PM)	9 V/m	
5785MHz (217Hz PM)	9 V/m		
RATED power frequency magnetic fields IEC 61000-4-8	50Hz or 60Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Criteria A

Comment:

The above listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the above listed models should assure that they are used in such an environment.

Input a.c. power PORT			
Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrical fast transient/bursts IEC 610004-4	± 2 kV 100kHz Repetition frequency	± 2 kV	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria B
Surges IEC 61000-4-5	$\pm 0,5$ kV, ± 1 kV line(s) to line(s) $\pm 0,5$ kV, ± 1 kV , ± 2 kV line(s) to ground (a)	± 1 kV , Differential mode ± 2 kV Common mode	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria B
Conducted RF induced by RF fields IEC 61000-4-6	10 Vrms 150 kHz - 80 MHz also ISM and Amateur Radio Bands c) 80% AM 1kHz	10 Vrms	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T ; 0°,45°,90°,135°,180°,225°,270°,315° 0% U_T ; 0° 0% U_T ; 70% 0% U_T ; 0%	0,5 Cycles 1Cycle 25/30 Cycles (50/60Hz) 250/300 Cycles (50/60Hz) (5s)	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. If the user of the above listed models requires continued operation during power mains interruptions, it is recommended that the above listed models are powered from an uninterruptible power supply or battery. Criteria A (max. Mains voltage) Criteria B (min. Mains voltage) Criteria A (max. Mains voltage) Criteria B (min. Mains voltage) Criteria A (max. Mains voltage) Criteria B (min. Mains voltage) Criteria B (max. Mains voltage) Criteria B (min. Mains voltage)

Comment:
a) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
b) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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Signal input/output parts PORT

Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±,8 kV Contact ± 2,4,8,15 kV Air	±8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Criteria B
Electrical fast transient/bursts IEC 610004-4 (a)	± 1 kV 100kHz Repetition frequency	± 1 kV	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria B
Surges IEC 61000-4-5 (b)	±2 kV line(s) to ground	± 2 kV , Common mode	N/A
Conducted RF induced by RF fields IEC 61000-4-6 (a)	10 Vrms 150 kHz - 80 MHz also ISM and Amateur Radio Bands c) 80% AM 1kHz	10 Vrms	Mains power quality should be that of a professional healthcare facility environment and Home healthcare environment. Criteria A

Comment: DC output port shall be considered as a signal port without connection directly to output cables.


a) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

b) This test applies only to output lines intended to connect directly to outdoor cables.

c) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Guidance and manufacturer's declaration - electromagnetic immunity

The above listed models are intended for use in the electromagnetic environment specified below. The customer or the user of the above listed models should assure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF induced by RF fields IEC 61000-4-6</p> <p>Radiated RF EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3</p>	<p>3 Vrms 150 kHz - 80 MHz 6Vrms ISM and Amateur Radio Bands (c)</p> <p>10 V/m 80 MHz – 2,7 GHz</p>	<p>10 Vrms</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should not be used no closer to any part of the above listed models, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p style="text-align: center;">Recommended separation distance</p> <p>$d = 1,2\sqrt{P}$</p> <p>$d = 1,2\sqrt{P}$ 80 MHz - 800 MHz $d = 2,3\sqrt{P}$ 800 MHz – 2,7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a should be less than the compliance level in each frequency range. (b)</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the above listed models are used, exceeds the applicable RF compliance level above, the above listed models should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the above listed models.

b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

c) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Recommended separation distances between portable and mobile RF communications equipment and the above listed models

The above listed models are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the above listed models can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the above listed models as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

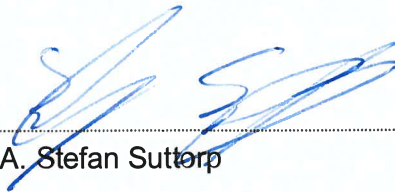
Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME Equipment or ME System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Date of issue: 2017-11-08

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ppa. Armin Wegener

Vice President Research & Development

A handwritten signature in blue ink, appearing to read "Stefan Suttorp".

i.A. Stefan Suttorp

Field Application Engineer Medical