

# IEC 60601-1-11:2015 Compliance

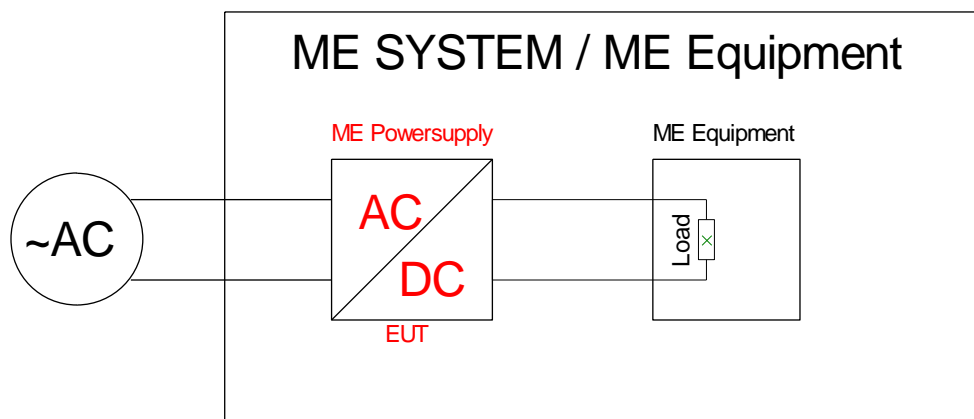
valid for the following models/model/families:

FW8002M (FOX6M), FW8000M (FOX12M), FW8001M (FOX18M), FW8030M (FOX30M), FW8030M/DT (FOX30-DM) FW8002M/USB (FOX6M-USB), FW8000M/USB (FOX12M-USB), all with IPx2 Primary Adapter

## MANUFACTURER:

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

## APPLICATION:



The ME power supply fulfills the following requirements of the **STANDARD**

## STANDARD

IEC / EN 60601-1-11:2015

## **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.

## **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 standard IEC60601-1-2: 2014. The compliance requirement to the IEC60601-1-2 is specified in a separate document.

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

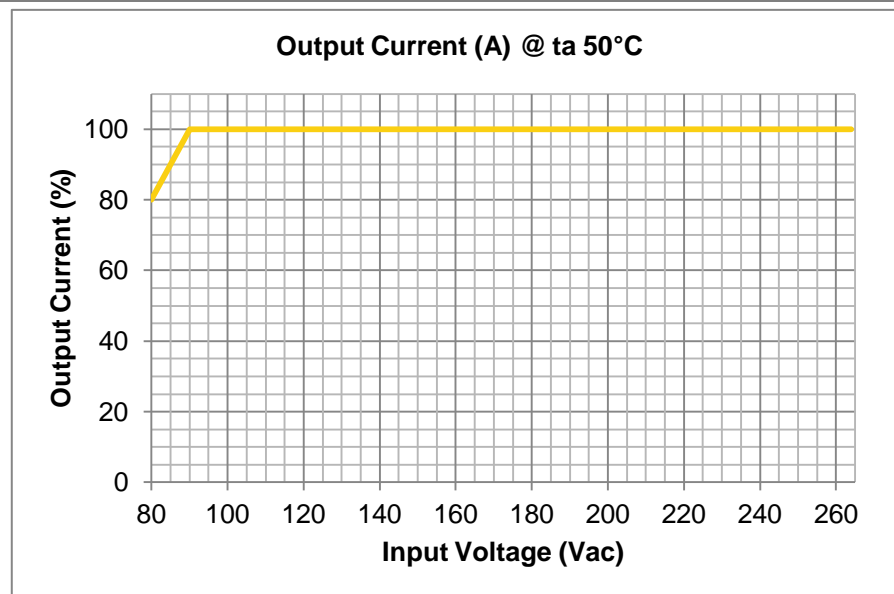
Please note and observe all attached information's with the exceptions and limitations.

## AC Input Voltage range

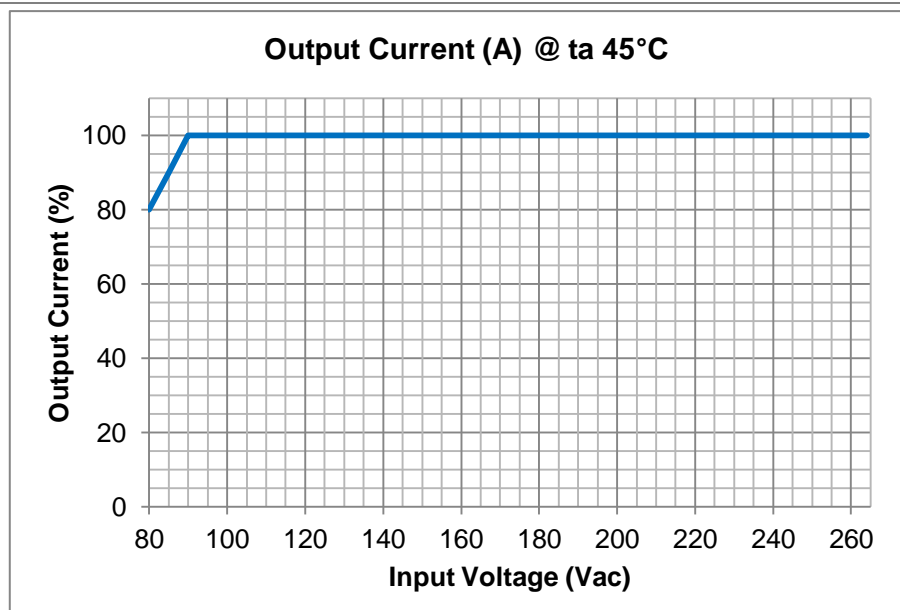
The power supply, supplies a defined output voltage and output current according to the specifications and instruction manual, in a range of 100-240V AC (-20%/+10%). The performance is reduced in the tolerance range. (See output power derating dependency of AC Input Voltage diagram)

### Output power derating dependency of AC Input Voltage

**FW**  
8001M



**FW**  
8000M, 8002M,  
8030M,  
8030M/DT,  
8002M/USB,  
8000M/USB



## Storage Condition

The power supply can be stocked under following conditions

<b>FW</b> 8000M, 8001M, 8002M,8030M, 8030M/DT, 8002M/USB, 8000M/USB	Storage Temperature	-40 ... +70 °C
	Storage humidity	10 - 95 % non condensing
	Atmospheric pressure	70-106 kPa

## Operating Condition

The power supply can operate under following conditions




<b>FW</b> 8000M, 8002M, 8030M 8002M/USB, 8000M/USB	Operating Temperature	0 ... +45 °C
	Humidity	10 - 95 % non condensing
<b>FW</b> 8001M	Operating Temperature	0 ... +50 °C
	Humidity	10 - 90 % non condensing
<b>FW</b> 8000M, 8001M, 8002M,8030M, 8030M/DT, 8002M/USB, 8000M/USB	Altitude	3000m
	Atmospheric pressure	70-106 kPa
<b>FW</b> 8030M, 8030M/DT	Altitude	4000m
	Atmospheric pressure	62-106 kPa

## IP Protection



The power supply fulfills the requirements of **IP 40** acc. IEC 60529.

It fulfills also higher grades of water ingress protection with restrictions of use and position of use.

### For protection against vertically dripping water (IP41)

<b>FW</b> 8030M/DT with plugged in AC mains cable and DC cable	<p style="text-align: center;"><i>Horizontal</i></p> 
<b>FW</b> 8000M/USB, 8002M/USB, with IPx2 interchangeable mains adapter and plugged in DC cable	<p style="text-align: center;"><i>Horizontal</i></p> 
	<p style="text-align: center;">Vertical (lead outled down)</p> 

### For protection against dripping water (IP42)

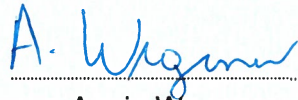
<b>FW</b> 8000M, 8001M, 8002M, 8030M with IPx2 interchangeable mains adapter and DC cable	<p style="text-align: center;"><i>Horizontal</i></p> 
	<p style="text-align: center;">Vertical (lead outled down)</p> 

## Mechanical stability

The power supply fulfills the mechanical stability requirements of the standards EN60601-1 and EN60601-1-11

<b>FW</b> 8000M, 8001M, 8002M,8030M, 8030M/DT, 8002M/USB, 8000M/USB	The Power Supply is non operable and portable during movement.	Bump (EN60601-1 15.3.2) Impact (EN60601-1 15.3.3) Drop (EN60601-1 15.3.4.1) Shock (EN60601-1-11 10.1.2 a) Vibration (EN60601-1-11 10.1.2 b) Removal of mold stresses (EN60601-1 15.3.6)
--	--	--

Date of issue: 2017-11-07

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

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