

# Technical Requirements for Medical Grade Power Supplies

Steve Roberts, RECOM Power, Austria



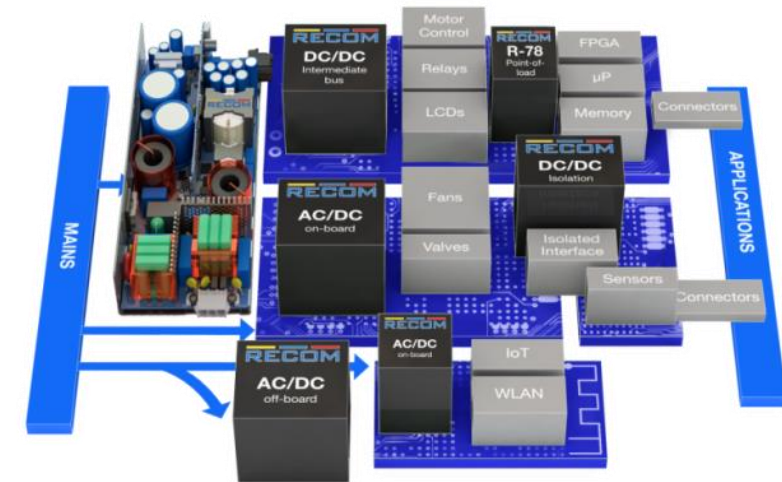
**MEDISCHE ELEKTRONICA**  
Ontwikkelingen, normen en toepassingen

6 februari 2024 | Van der Valk Vianen

# RECOM – A global success story for almost 50 years



- RECOM is a leading brand for innovative AC/DC and DC/DC converters for industrial, transport and medical markets
- RECOM is one of the fastest growing power companies, manufacturing 23M converters annually (2022)
- 30,000 products in the portfolio, 50+ new products/year (2022)
- R&D departments in Gmunden, Vienna, Italy and Xiamen
- Rutronik has been a key distribution partner for more than 30 years



# RECOM - Global Structure

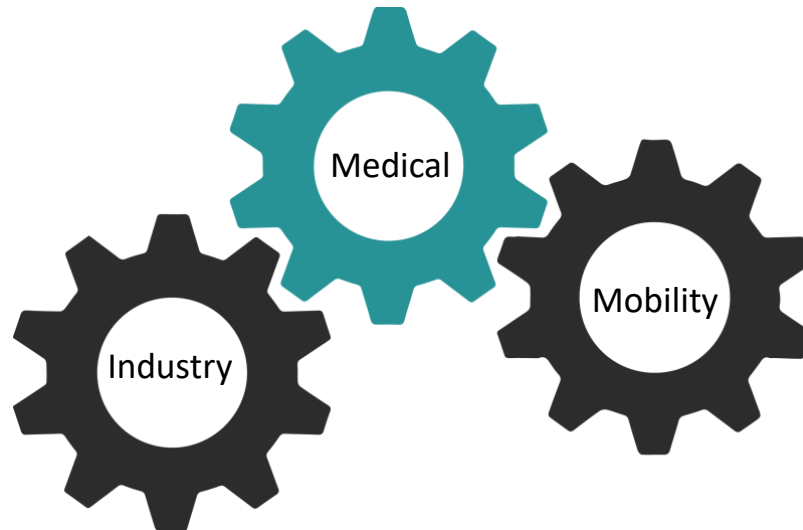


# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

- 1: Intended use is for medical equipment (ME)
- 2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard
- 3: Complies with IEC EN ANSI/AAMI 60601-1-2 EMC standard
- 4: Compatible with the Medical Device Regulation (MDR)

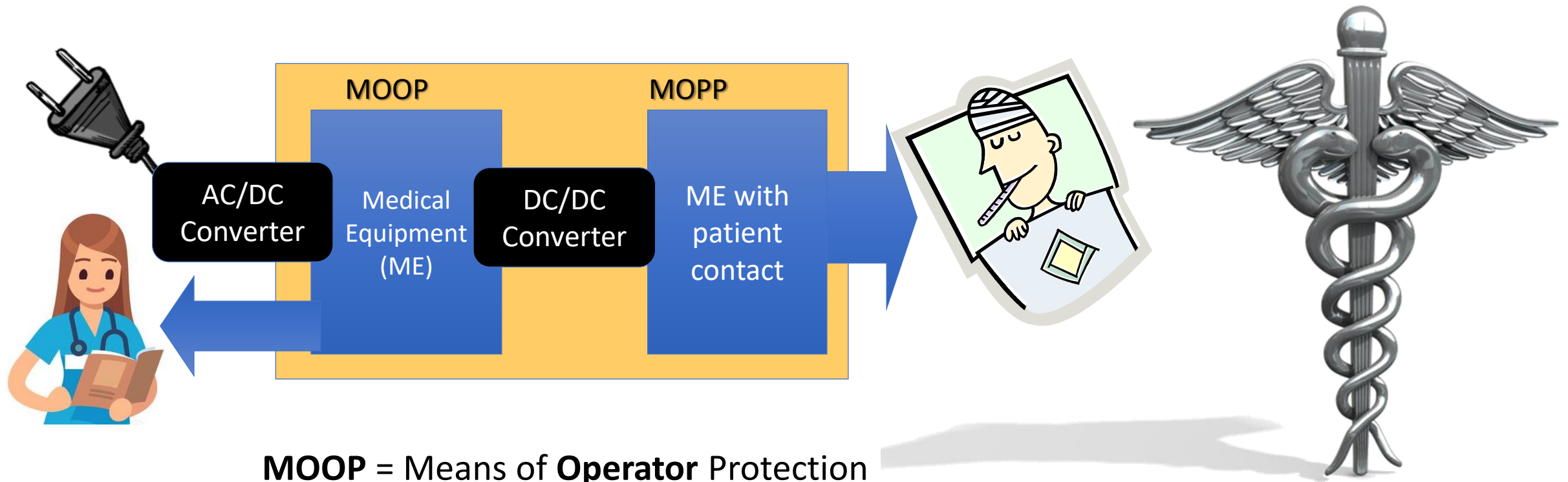


# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

1: Intended use is for medical equipment (ME)



**MOOP** = Means of **O**perator Protection

**MOPP** = Means of **P**atient Protection

# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard

**HBSE (Hazard-Based Safety Engineering)**

Isolation Grade	MOOP			MOPP		
	Clearance	Creepage	Isolation*	Clearance	Creepage	Isolation*
AC Basic (1 x MOP)	2.0mm	3.2mm	1 500VAC	2.5mm	4.0mm	1 500VAC
<b>AC Reinforced (2 x MOP)</b>	<b>4.0mm</b>	<b>6.4mm</b>	<b>3 000VAC</b>	<b>5.0mm</b>	<b>8.0mm</b>	<b>4 000VAC</b>
DC Basic (1 x MOP)	1.0mm	2.0mm	1 000VAC	1.0mm	2.0mm	1 500VAC
<b>DC Reinforced (2 x MOP)</b>	<b>2.0mm</b>	<b>4.0mm</b>	<b>2 000VAC</b>	<b>2.0mm</b>	<b>4.0mm</b>	<b>3 000VAC</b>

\* Isolation withstand test voltage, applied for 60s

**MOP: Means of Protection**

**2MOOP = 2 x Means of Operator Protection**

**2MOPP = 2 x Means of Patient Protection**



# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

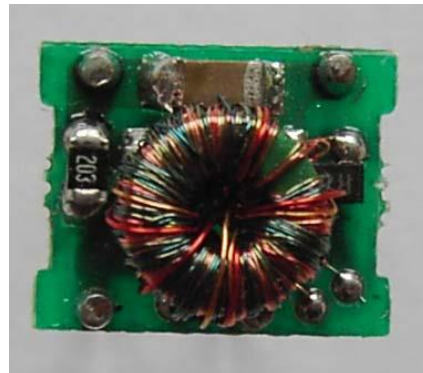
2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard

**For 2MOPP/2MOOP, Reinforced Isolation is a must**

**Insulation Grade** describes the type of isolation:

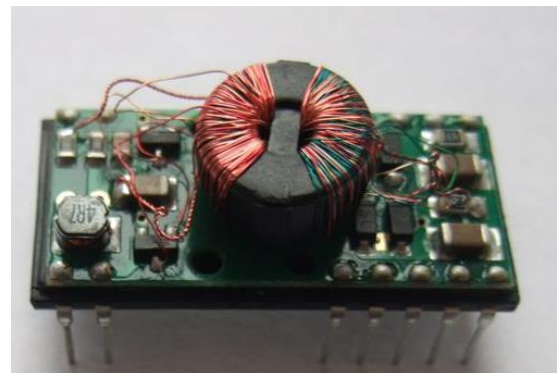
There are three classes:

- Functional insulation
- Double or basic insulation
- Reinforced insulation



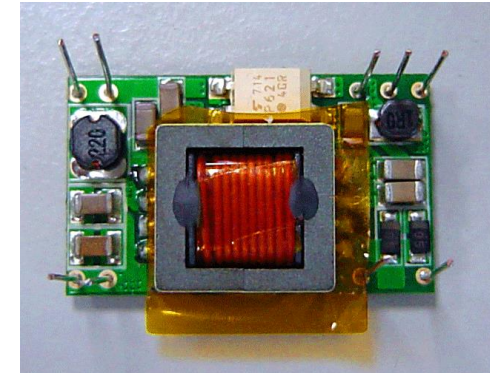
Functional isolation

(up to 4 kVDC / 1s  
or 2 kVAC/1min. )



Double isolation

(up to 6.4 kVDC / 1s  
or 3.2 kVAC/1min.)



Reinforced isolation

(up to 20 kVDC / 1s  
or 12.5 kVAC/1min.)

# Medical Grade Power Supplies



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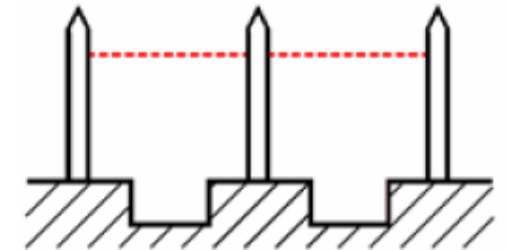
2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard

Requires enhanced creepage and clearance separations compared to industrial requirements

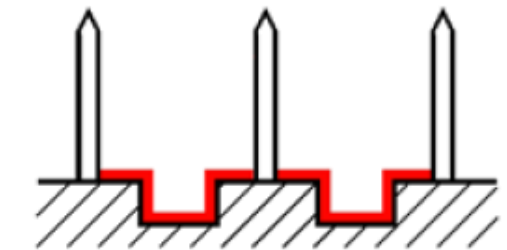
Clearance is the shortest distance between two points in air

Creepage is the shortest distance between two points along a surface

Clearance =



Creepage =



Isolation Grade	MOOP			MOPP		
	Clearance	Creepage	Isolation*	Clearance	Creepage	Isolation*
AC Basic (1 x MOP)	2.0mm	3.2mm	1 500VAC	2.5mm	4.0mm	1 500VAC
AC Reinforced (2 x MOP)	4.0mm	6.4mm	3 000VAC	5.0mm	8.0mm	4 000VAC
DC Basic (1 x MOP)	1.0mm	2.0mm	1 000VAC	1.0mm	2.0mm	1 500VAC
DC Reinforced (2 x MOP)	2.0mm	4.0mm	2 000VAC	2.0mm	4.0mm	3 000VAC



# Medical Grade Power Supplies



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2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard

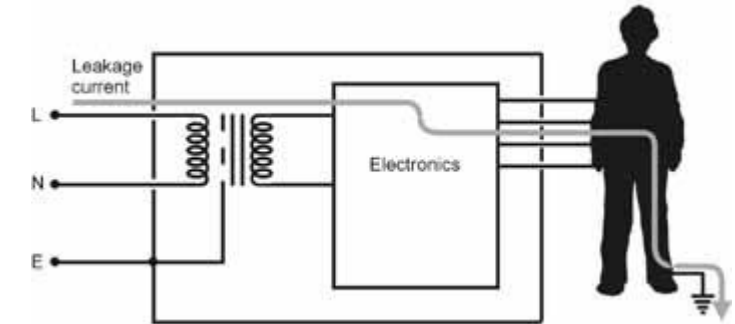
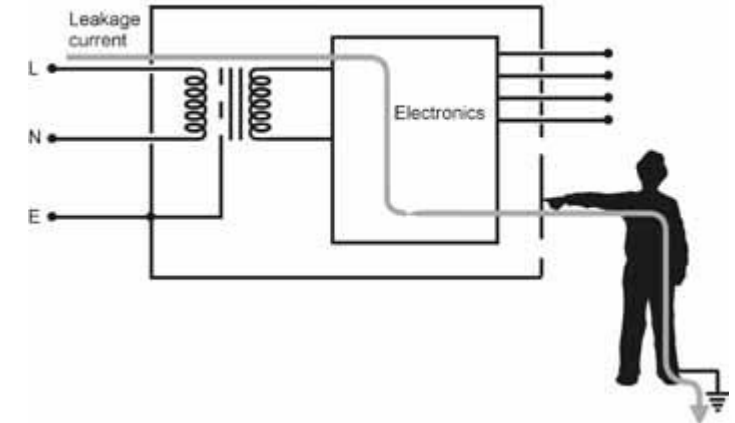
**Demands very low leakage currents**

Leakage Path	Typ B		Typ BF		Typ CF	
	NC	SFC	NC	SFC	NC	SFC
Ground	500 $\mu$ A	1mA	500 $\mu$ A	1mA	500 $\mu$ A	1mA
Housing	100 $\mu$ A	500 $\mu$ A	100 $\mu$ A	500 $\mu$ A	100 $\mu$ A	500 $\mu$ A
Patient	100 $\mu$ A	500 $\mu$ A	100 $\mu$ A	500 $\mu$ A	10 $\mu$ A	50 $\mu$ A

Type B (Body): Devices without direct patient contact

Type BF (Body Float): Devices with physical contact to the patient

Type CF (Cardiac Float): Devices for direct use on the human heart



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RM-File

Detailed risk assessment for a Risk Management (RM) file necessary

Risk Index Matrix

Severity rank \ Probability rank	1	2	3	4	5
5	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, high risk	Unacceptable, extreme risk	Unacceptable, extreme risk
4	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, high risk	Unacceptable, high risk	Unacceptable, extreme risk
3	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, high risk	Unacceptable, high risk
2	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, moderate risk
1	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk

Risk (index) acceptability level..... Risk=Severity x probability  
Result: Risk=1~6, acceptable; 7~25, unacceptable

IMDF - 069	<b>EU and UK Risk Assessment Report</b> (according to CENELEC GUIDE 32:2014)	
Version 1.0 24.01.2023 Author: APRO	<b>RACM30-K/277</b>	ISO 9001 Page 1 of 11

Version	Date	Changes	Author
0.0	19.09.2019	Draft	APRO
1.0	10.01.2020	Approved by IMS	APRO
2.0	20.05.2021	Adding Rationales and reference to source	APRO
2.1	10.11.2021	Rephrasing the introduction	APRO
2.2	20.12.2021	Adding EN IEC 63000 for RoHS-Assessment	APRO
2.3	10.06.2022	Adding UK topics to cover risks for UKCA mark (British standards and regulations)	APRO

Version	Date	Changes	Author
0.0	30.11.2022	Draft	APRO
1.0	24.01.2023	Approved by PCPO	APRO

**RACM30-K/277 Series**

Company Name	Recom Engineering GmbH & CO KG
Address	Muenzfeld 35, 4810 Gmunden, Austria
Product Name	Built-in AC/DC
Model and / or Type Reference	See the following pages
Accessories	None
Report Number	R2301001
Date	24-Jan-2023

Evaluator Signature: Tobias Endler

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Valid for <input type="checkbox"/> RECOM Power <input type="checkbox"/> RECOM Engineering <input type="checkbox"/> RECOM Electronic	Cross references:	Addressed to: all RECOM departments
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# Medical Grade Power Supplies

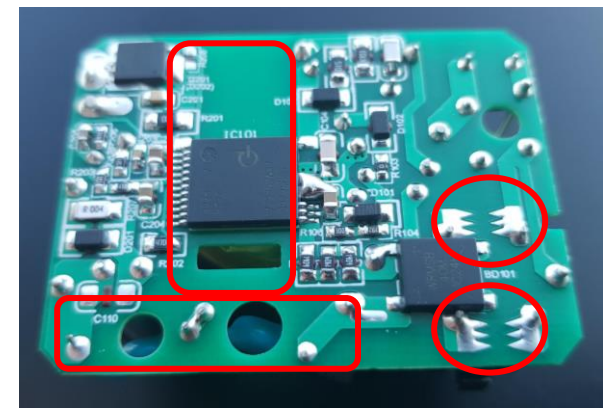


What differentiates a medical power supply from an industrial power supply?

2: Complies with IEC EN ANSI/AAMI 60601-1 safety standard

How do these safety requirements affect the physical design of the power supply?

- Reinforced insulation (e.g. triple insulated transformer wires)
- Increased insulation test voltage (thicker insulation 4 kVAC/1min)
- Increased transient test voltage (spark gap)
- Larger creepage and distance separations (8mm/5mm)
- Single Point of Failure Analysis e.g. two Y capacitors in series



# Medical Grade Power Supplies



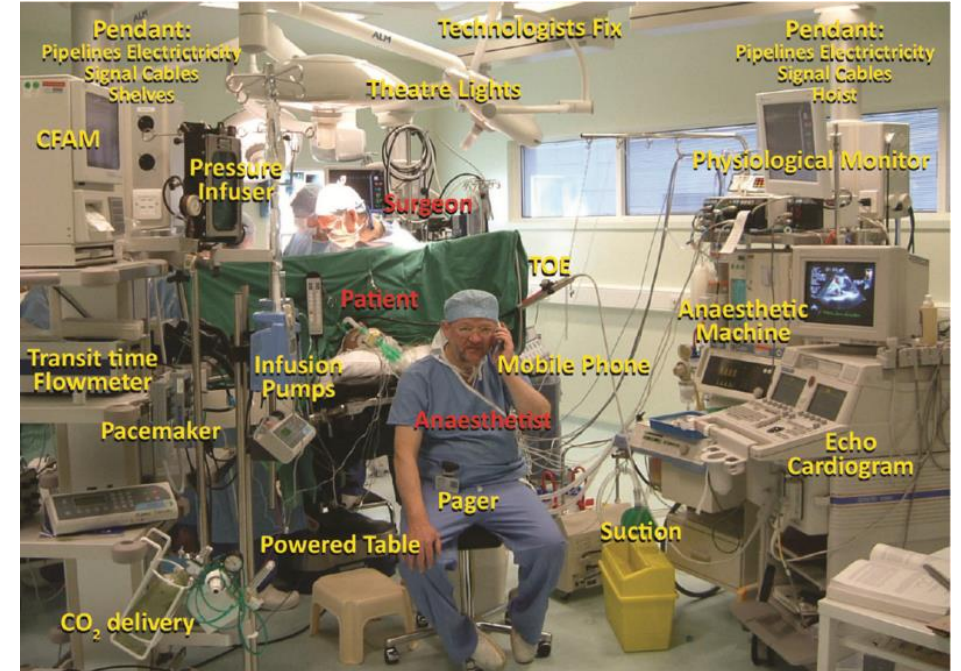
What differentiates a medical power supply from an industrial power supply?

3: Complies with the EMC standard IEC EN ANSI/AAMI 60601-1-2

## Stricter EMC limits

The EMC limits for ME are stricter than for equivalent industrial devices.

This reflects the real situations in which medical products are used: healthcare professionals today use many more electronic devices per patient to ensure better monitoring and diagnosis, so the likelihood of interference between two devices has increased.



# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

3: Complies with the EMC standard IEC EN ANSI/AAMI 60601-1-2

## Stricter EMC limits

The EMC limits for ME are stricter than for industrial devices.

Medical devices are increasingly used outside of the relatively EMC friendly and controlled hospital environment in other settings such as the home (telemedicine), in an ambulance, or even in a mall clinic, where cross-interference is more likely.



# Medical Grade Power Supplies



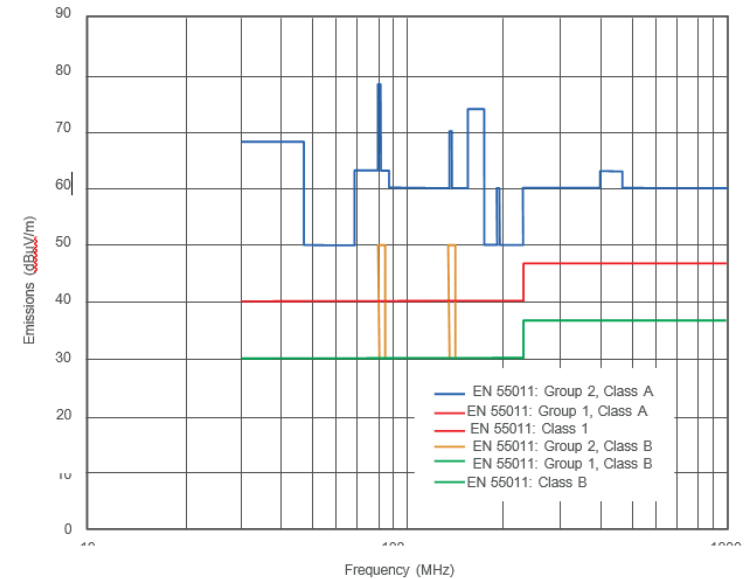
What differentiates a medical power supply from an industrial power supply?

3: Complies with the EMC standard IEC EN ANSI/AAMI 60601-1-2

## Class B stricter than Class A

Medical EMC emission and interference immunity protection has different groups and limits compared to industrial EMC limits:

Class A applies to professional healthcare facilities (hospitals, clinics, operating rooms, etc.) and is the easier level to meet as these environments are assumed to be “quiet” and well controlled. Class B is for home health care. This level is more severe because these environments are assumed to be “noisy” and less well controlled.





What differentiates a medical power supply from an industrial power supply?

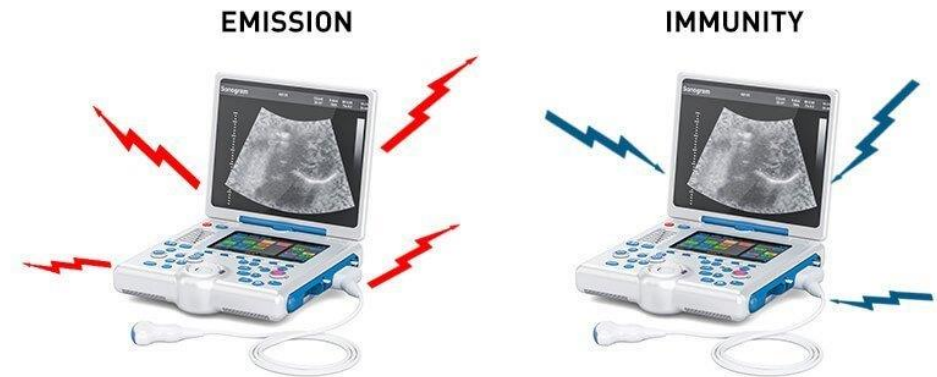
3: Complies with the EMC standard IEC EN ANSI/AAMI 60601-1-2

## Safe Operation under EMI Conditions

Medical devices must perform their intended function and remain safe (meet their essential performance and essential safety) under all normal operating conditions.

The effects of electromagnetic interference can range from mildly annoying (flickering on a display) to device malfunctions (false alarms, irregular readings) to catastrophic events (equipment failure, patient harm).

Medical Equipment (ME) must often also meet IEC TS 60601-4-2 :  
Electromagnetic immunity: Performance Requirements.



# Medical Grade Power Supplies

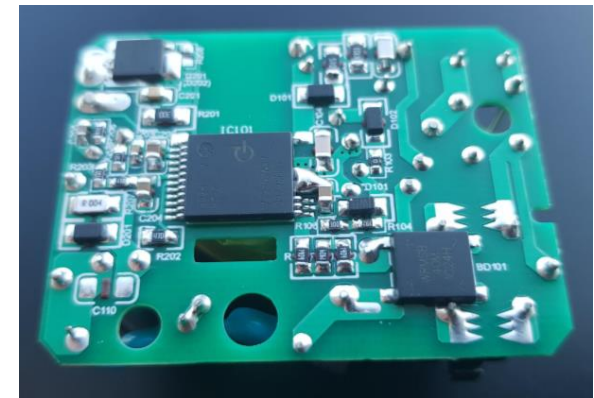


## What differentiates a medical power supply from an industrial power supply?

3: Complies with the EMC standard IEC EN ANSI/AAMI 60601-1-2

## How do these EMC requirements affect the physical design of the power supply?

- Improved filtering to reduce conducted emissions and susceptibility, effects of ESD, transients and power surges.
- Circuit and layout changes (slower switching edges, spread spectrum frequency dithering, optimized transformer parasitics) to reduce radiated emissions and susceptibility
- The operating instructions must consider the risks of EMI from other devices, e.g. by specifying how close two devices may be placed together.



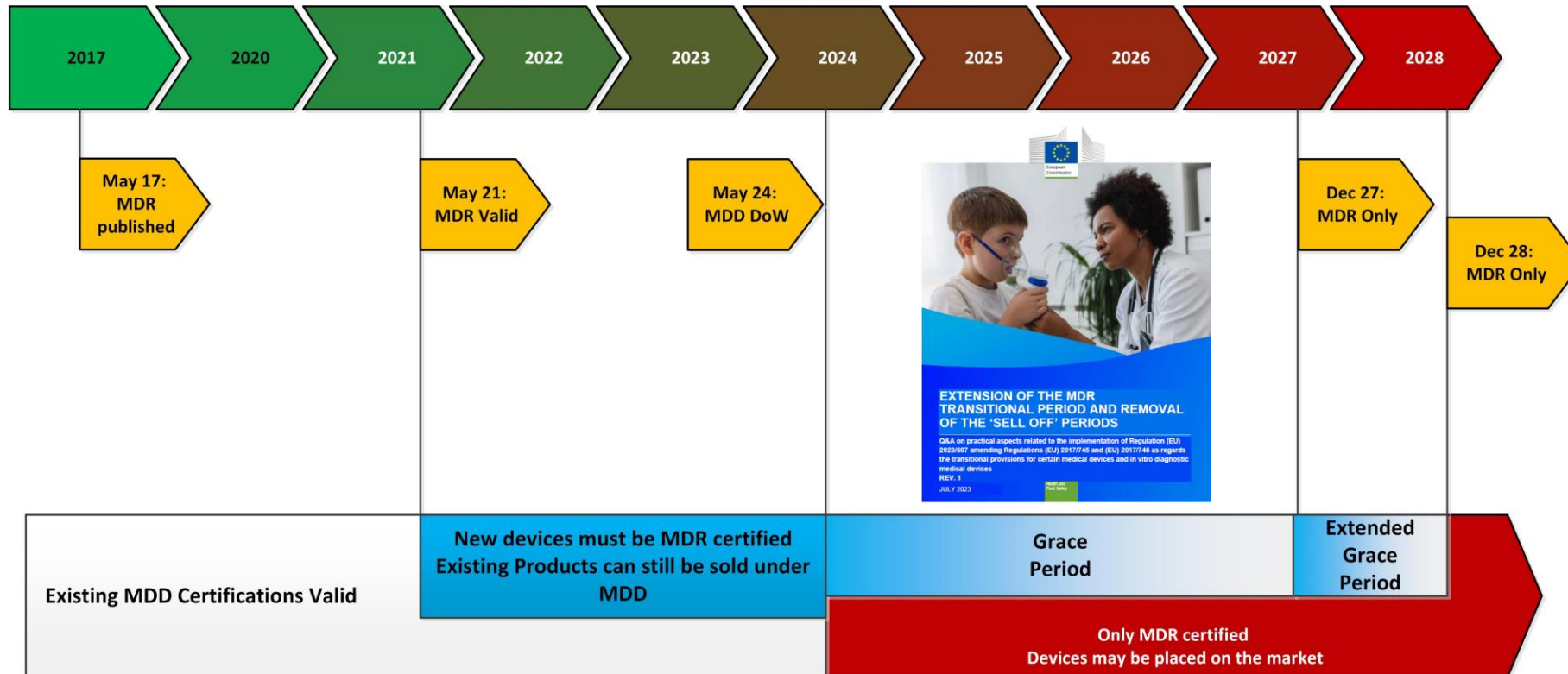


# Medical Grade Power Supplies



What differentiates a medical power supply from an industrial power supply?

## 4: Compatible with the Medical Device Regulation (MDR)



# Medical Grade Power Supplies



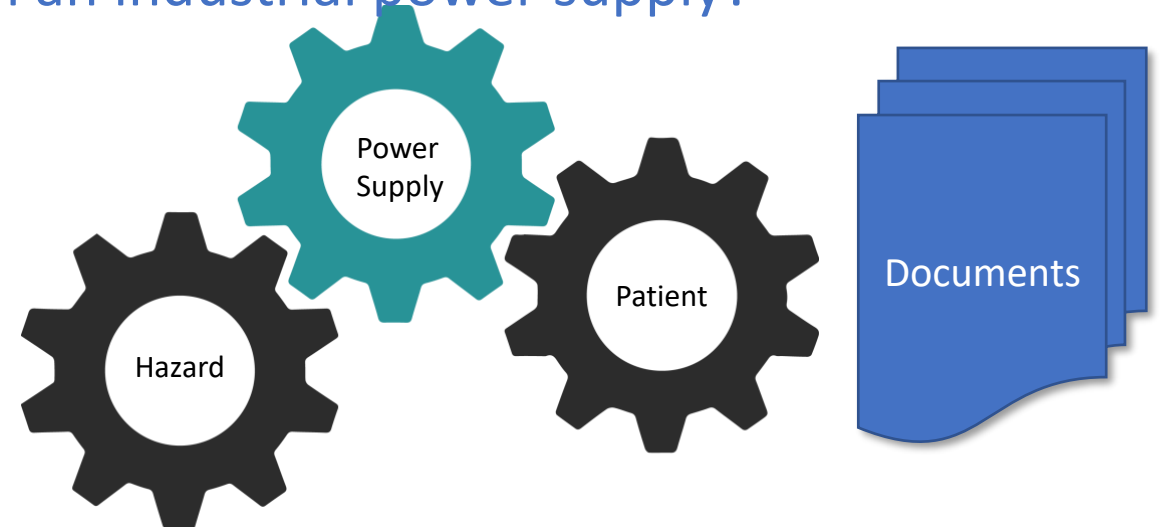
## What differentiates a medical power supply from an industrial power supply?

4: Compatible with the Medical Device Regulation (MDR)

Power supplies are not medical devices per se, but are critical components for patient and operational safety.

The medical device manufacturer therefore needs proof that the power supply is MDR-compliant.

**The documentation is part of the product!**



- 60601-1 Safety documentation (Conformity certificates, Operating instructions, RM-File, etc.)
- 60601-1-2 EMC documentation (Conformity certificates, Operating instructions, Test results, etc.)
- Quality Control documentation (Production QC, Supplier audits, SOP instructions)
- Product informationen (Product Label, Datasheets, Responsible persons, Product lifecycle)
- Serial number (Traceability, Individual test reports, Component QC records)

# Medical Grade Power Supplies

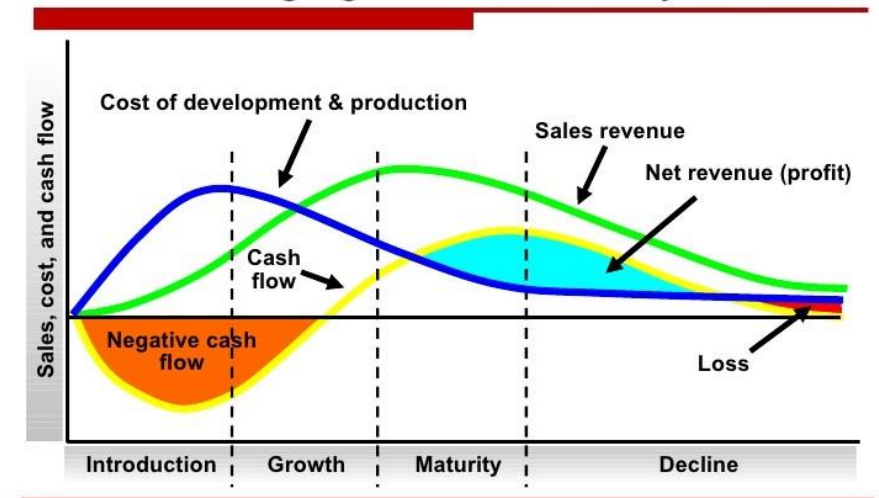


## What differentiates a medical power supply from an industrial power supply?

### Summary:

- When developing a new medical power supply product, stricter safety and EMC requirements change the physical design.
- So, before you start, decide on the application because a medical power supply can be used in an industrial application, but not the other way around.
- Documentation is part of the product!
- Plan for the long term – a medical grade power supply manufacturer's responsibility extends over the entire product life cycle.
- Choose a reliable long-term supplier such as Rutronik to support you with your medical project, so that you make the best choice and get the best technical and documentation support.

### Managing Product Life Cycle





Q&A

Please visit us at  
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more information



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