



Schaffner Group

# Medical Solutions

# Agenda

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## Medical Product Requirements for EMI Filters

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### Chokes

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**FN9262/FN9266**

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**FN9255**

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**FN9274**

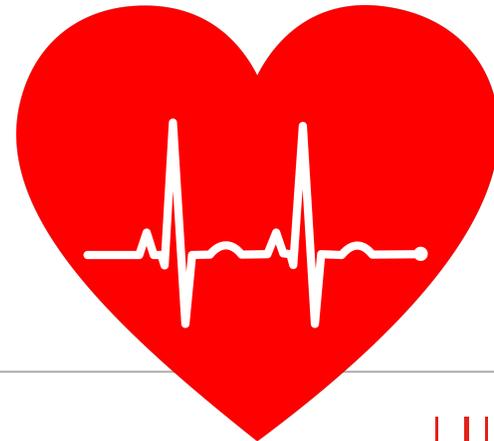
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# When every heart beat counts

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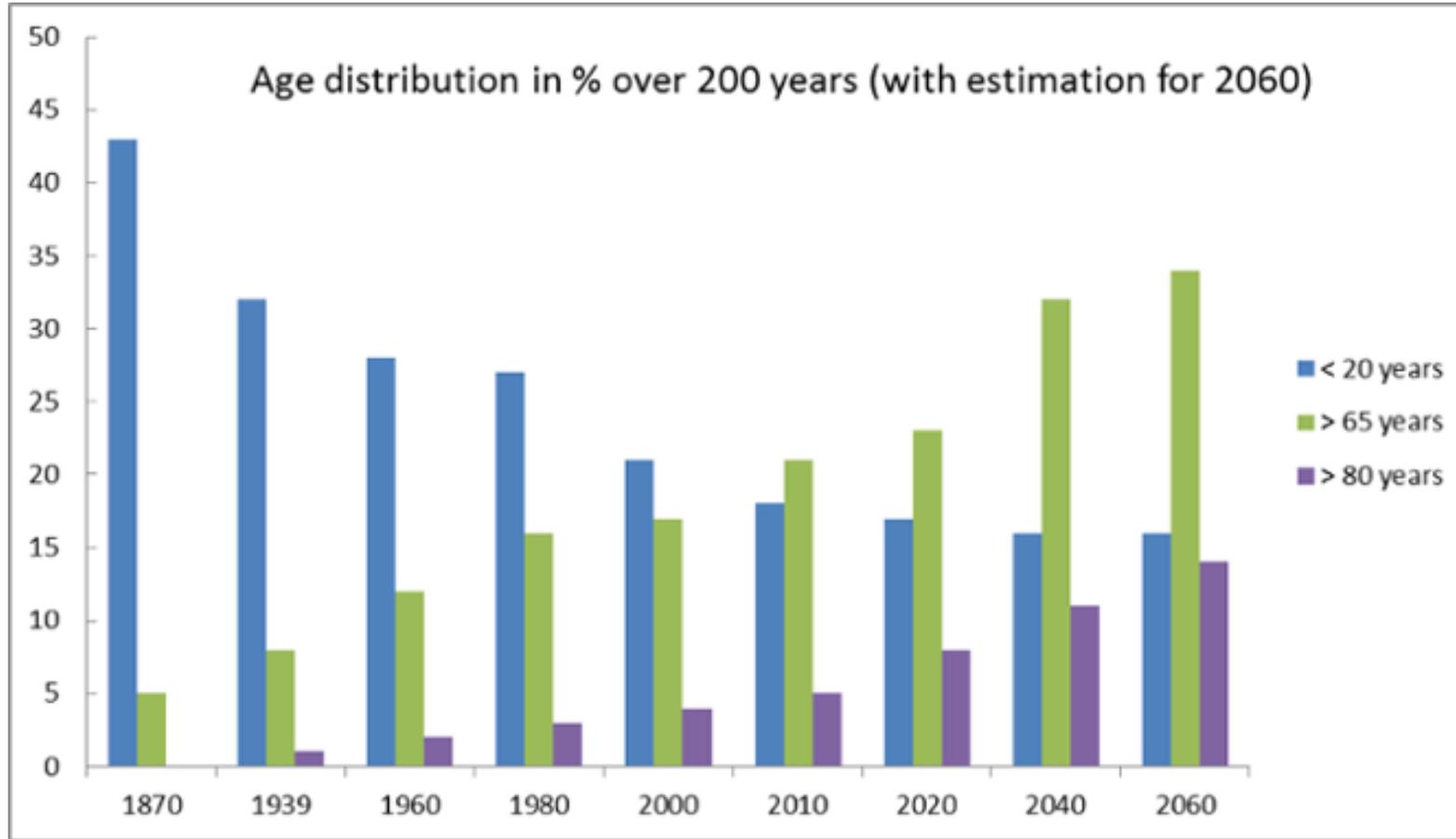
- What is the relationship to EMC/EMI?
  - Electrification and number of electronic medical devices in hospitals is rising  
This generates more Electro Magnetic Interference (EMI)
  - High power installations like in robot-aided surgery or X-ray systems are used close to imaging diagnostics  
Electro magnetic compatibility is therefore more and more important
- Imagine a doctor how is not able to use an electrocardiogram because of other devices interfering
  - With Schaffner Filters you can make sure that

**EVERY HEART BEAT IS COUNTED**



# Why do we see a big market in medical devices?

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QUITE EASY:

- | People are getting older
- | New technologies enter
- | Cost of medical care increases
- | All three points lead to:

**Moving more in the home care sector, which leads to high volume**

BTW: Any electronic device in the market needs to fulfill EMC/EMI limits and applications specific safety standards

# IEC60601-1 applied to RFI Filters

- In general filters are developed and certified according to a Filter Standard: IEC 60939-3 and UL 60939-3
- With knowledge in the application specific standards, we are able to design accordingly
  - Implementation of

**IEC 60601-1** - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

specifics is approved by certifying bodies and presented in the certification of the filter standard:

“The filters in B-Version, complies with the requirements of the standard EN/IEC 60601-1 regarding creepage and clearance distances, leakage current and voltage.”



IEC 60601-1

Edition 3.0 2005-12

**INTERNATIONAL  
STANDARD**  
NORME  
INTERNATIONALE

Medical electrical equipment –  
Part 1: General requirements for basic safety and essential performance  
Appareils électromédicaux –  
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

# Schaffner EMC vs. application specific RFI disturbances

- Schaffner is known as the world leader in design of EMI/EMC filters
- It is possible that our filters and their performance exceed customer expectations
- BUT:
  - The disturbance level and therefore the filter performance can only be defined together with the customer, as
  - We don't know the exact performance demand of a customer system and we are not good in fortune telling
  - We are good in filter design based on communicated customer expectations and specifications
- Our filters comply with general safety standards, but we are not able to comply to EMC/EMI limits without a surrounding system as our filters are “only” components
- Therefore new edition of standard IEC 60601-1-2:2014 Edition 4 does not apply to our filters



# Leakage current limits

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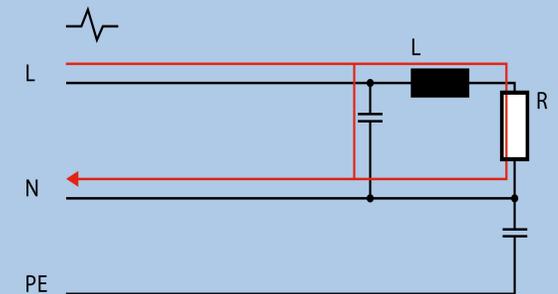
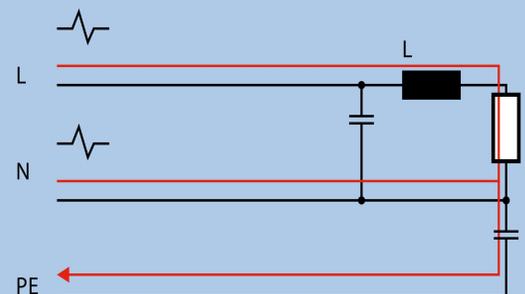
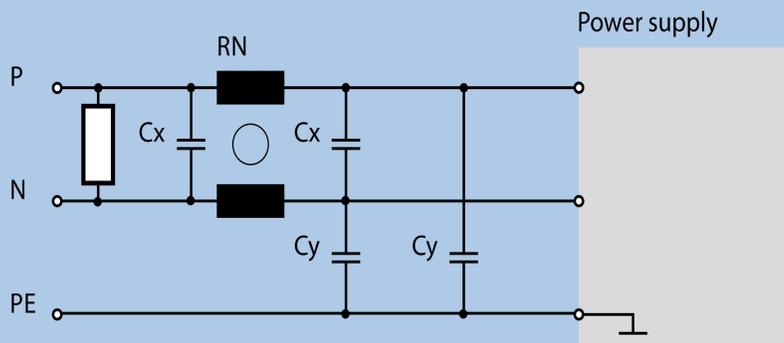
- Class CF is the most severe class in terms of patient safety definition:
  - Requires 2 MOPP (Means of patient protection), directly linked to double or reinforced insulation
  - Can be used in direct cardiac applications, to reduce the limit of ventricular fibrillation patient leakage current limits are:
    - Normal condition: 10uA → total patient leakage current needs to be below 50uA
    - Single fault: 50uA → total patient leakage current in single fault needs to be below 100uA

$$I_{LK} = 2\pi \times f_R \times U_R \times C_y$$

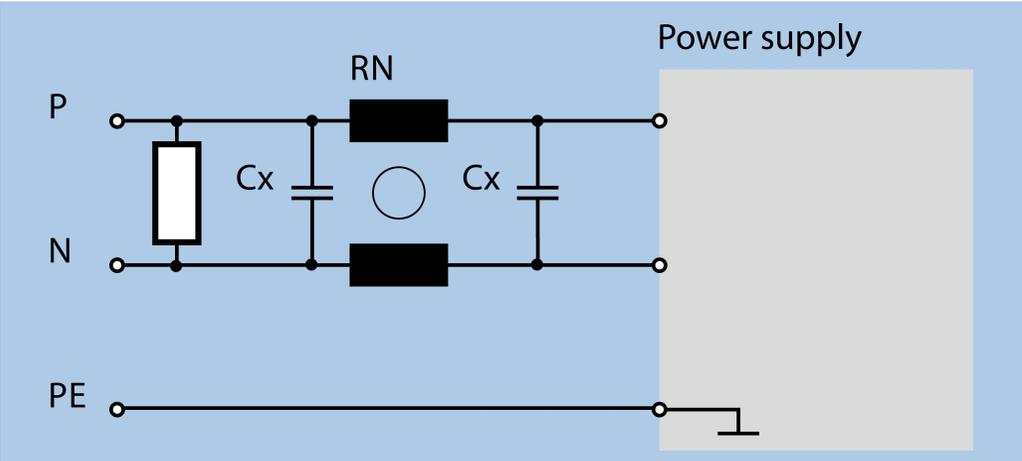
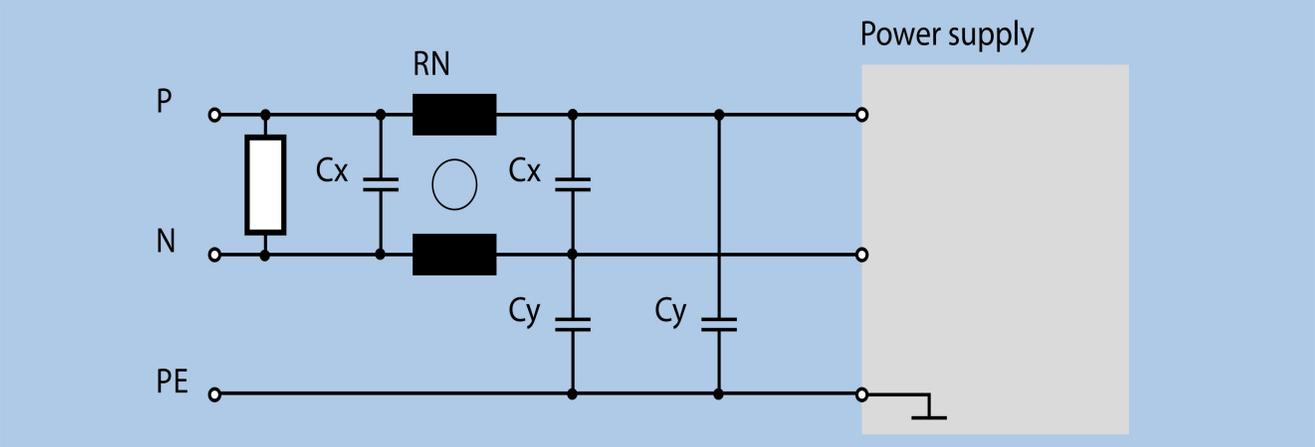
- With a limit of 10uA, supplied from grid voltage (230VAC, 50Hz) the  $C_y$  needs to be below: approx. 100pF which is already in the region of parasitic effects → NO CAP to EARTH

# Leakage current vs. performance

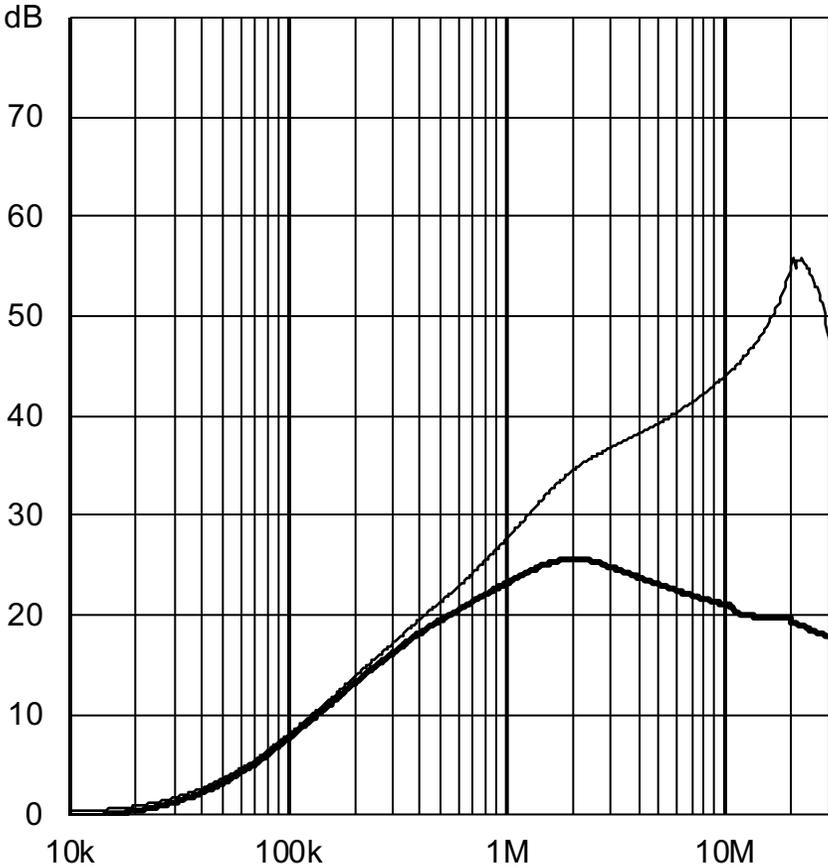
- Talking about EMI performance of a system, leakage current plays a big role in medical devices
- In regards to the standard, leakage current limitation is clearly defined
- Easiest approach is:
  - Add NO leakage current to a system, in order to limit patient risk of an unintentionally applied touch or leakage current
- Short excursion to EMI filtering:
  - Two different kinds of disturbances: Common (CM) and differential mode (DM)
  - CM – asymmetrical - between lines and PE – common mode choke and Y-Caps
  - DM – symmetrical - between lines – differential mode choke and X-Caps



# Leakage current vs. performance

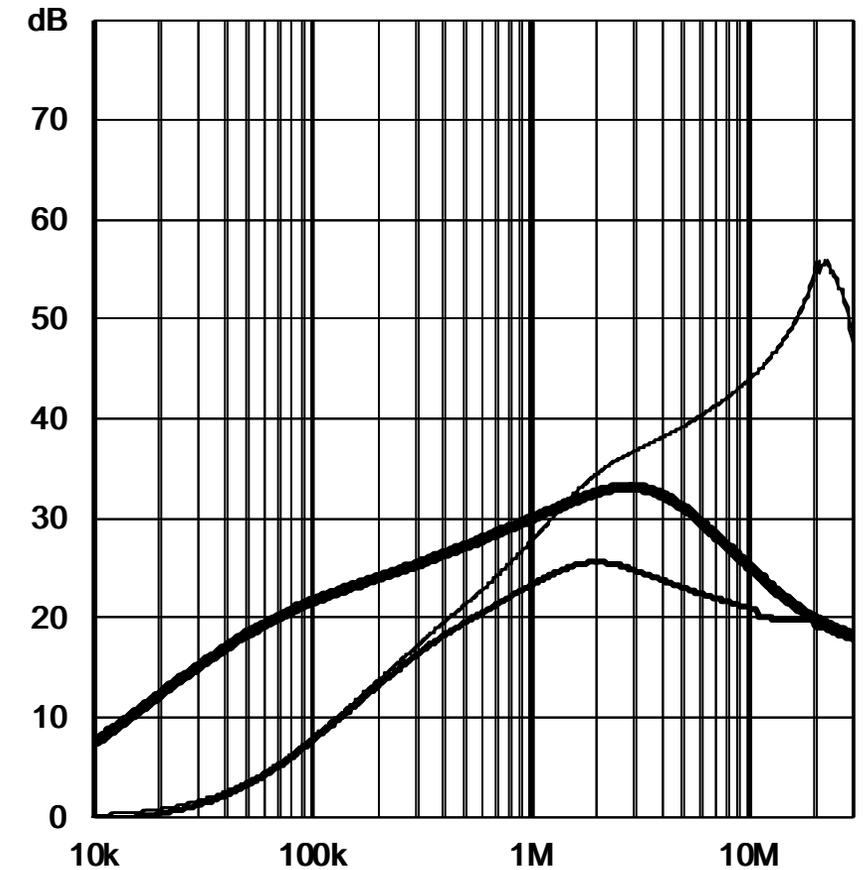
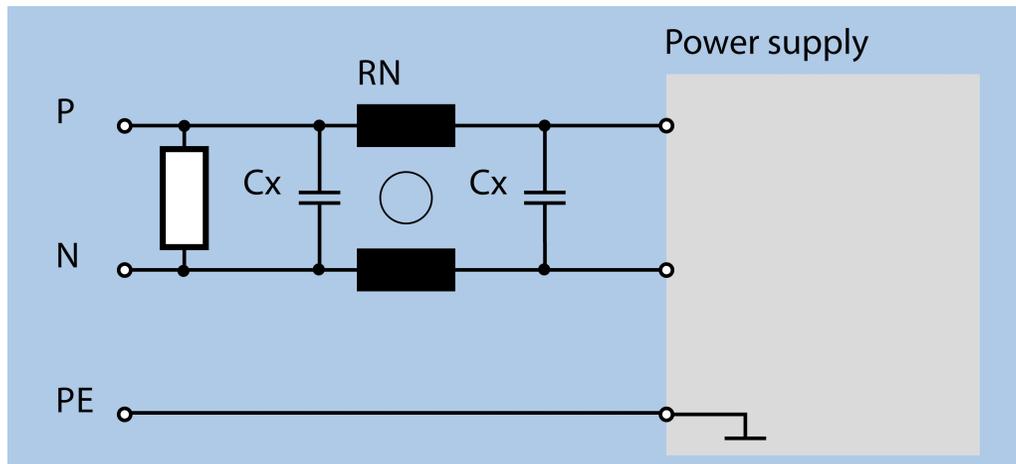


Comparison of standard to medical (B-) type



# Leakage current vs. performance

- Nano crystalline material is best to get better performance  
In the same housing without the need for Y-Caps
- NEW Product is available: FN 9262/6
  - With fuses and high performance best fit for medical application



# Class I vs. Class II ME (Medical Equipment)

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- Class I and II differ in the earthing concept and the insulation system
  - Class I: Basic Insulation plus protective earth
  - Class II: Reinforced insulation with allowed functional earth (no protective earth)
- For IEC Inlets that means:
  - Class I can be maintained with usual IEC C13/14 connection with protective earth pin
  - Class II could be maintained with the description of the earth pin as functional earth, but easier:
    - Using IEC C17/18 makes it clear that no protective earth is available



- Together with increased distances (creepage and clearance) Schaffner is going to introduce a new IEC inlet filter series for class II ME

# Chokes

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- EMI Filter Design on Component level can feature all medical relevant EMI Filter designs
  - NO Leakage current introduced by the choke
- Schaffner is offering a wide variety of Chokes to comply with IEC 60601-1
  - This is not certified since the chokes needs to be certified in the hole system



# FN9262/64

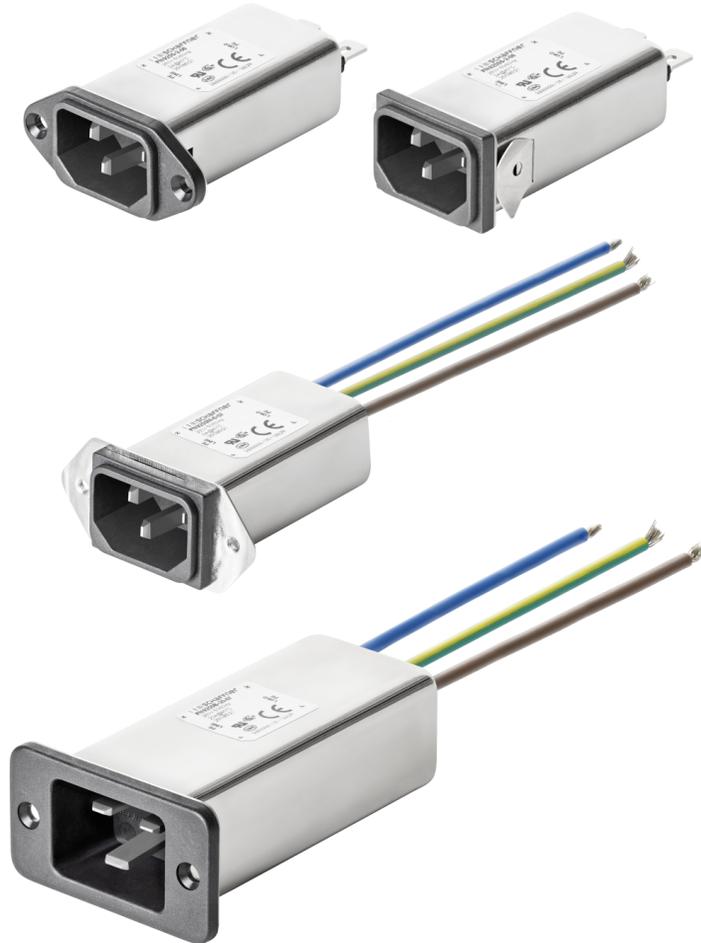
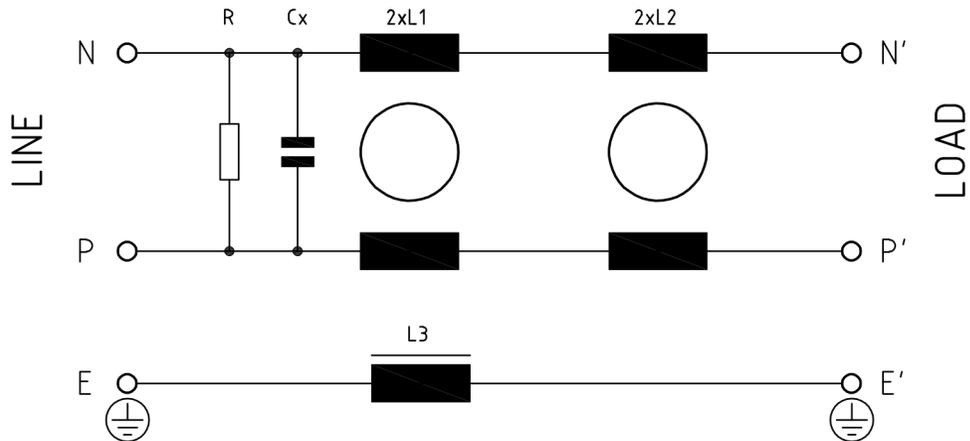
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- Increased performance compared to FN9260/4  
>1mH at 10A with new core technology
- Features high performance without Cy (B-Type)
- Best fit to medical application if fuse or switch is needed
- Easy to be used in general applications for e.g. ventilators with defined IP levels



# FN9255

- Very high performance in upper frequency range
  - Beyond 1MHz
- Version with 16A/20A Inlet available
- EB Type with increased performance without  $C_y$  available
  - Featuring earth line choke

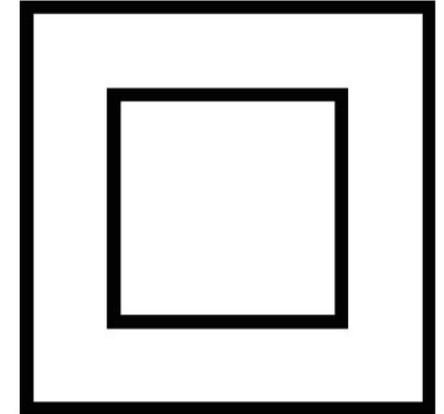


# New product to be introduced – FN9274B

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- First IEC Inlet at Schaffner to feature Class II for medical application
- Customer benefits:
  - Class II
  - 2MOPP
  - Inlet without Earth (C17/C18)
  - High performance
  - Plastic housing for easy and safe installation



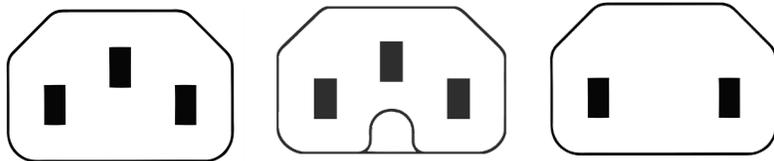
# IEC Inlets available

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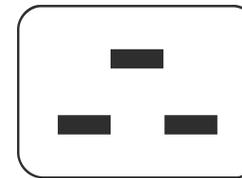
- Due to high demand of IEC inlets and Schaffner's expertise in manufacturing and design of such inlets, we are able to provide a high variety of possible inlets without a filter

All are available for front, rear and snap mounting, including the following standards according to IEC 60320/UL 498:

C14, C16 and C18 suitable for general purpose applications up to 10A acc. to IEC 60320 and up to 15A acc. to UL 498



C20 suitable for general purpose applications up to 16A acc. to IEC 60320 and up to 20A acc. to UL 498



C14 version including various other features like fuse holder, switch, voltage selector or combination of all are also available.