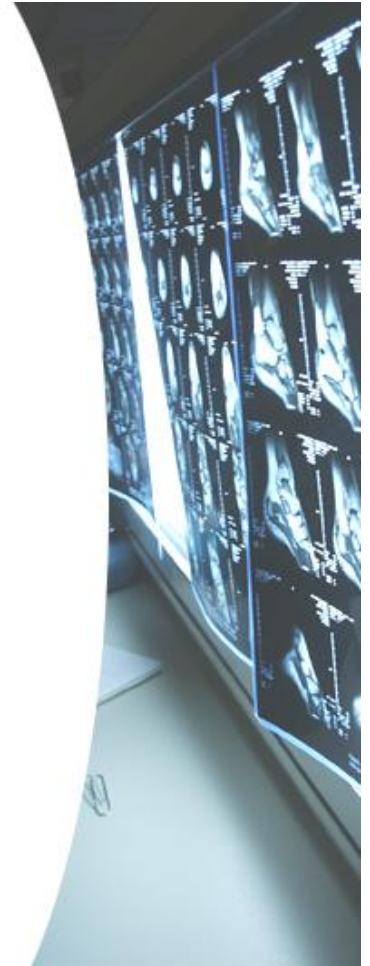


Medical Information technology

Information for manufacturers, resellers and users



- ***A Medical PC ... what does that mean?***
- An excursion into the world of electrotechnology
- A case study based on a room - plan
- Baaske Datentechnik e.K. products for electrical safety

A so called „Medical PC“ ...

... is a computer with medical norm certificate

... is equipped with a medical approved power supply with very low leakage current values (IEC 60601-1 Safety)

... is resistant against electromagnetic interferences (EMI) (IEC 60601-1-2 EMC)

... does not emit any electromagnetic interferences by itself (IEC 60601-1-2 EMC)

... is individually tested for IEC 601 in line production



A so called „Medical PC“ is...

... under specific conditions applicable to be combined with active medical products

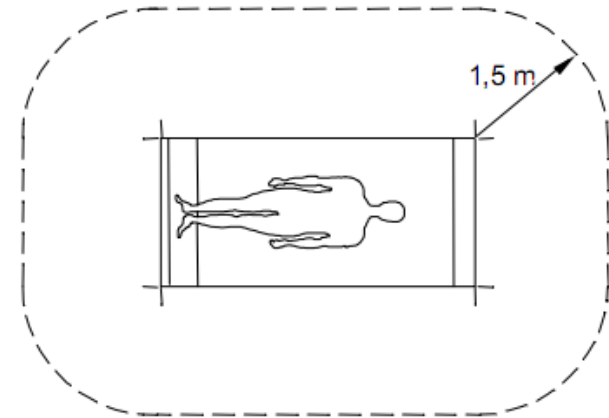
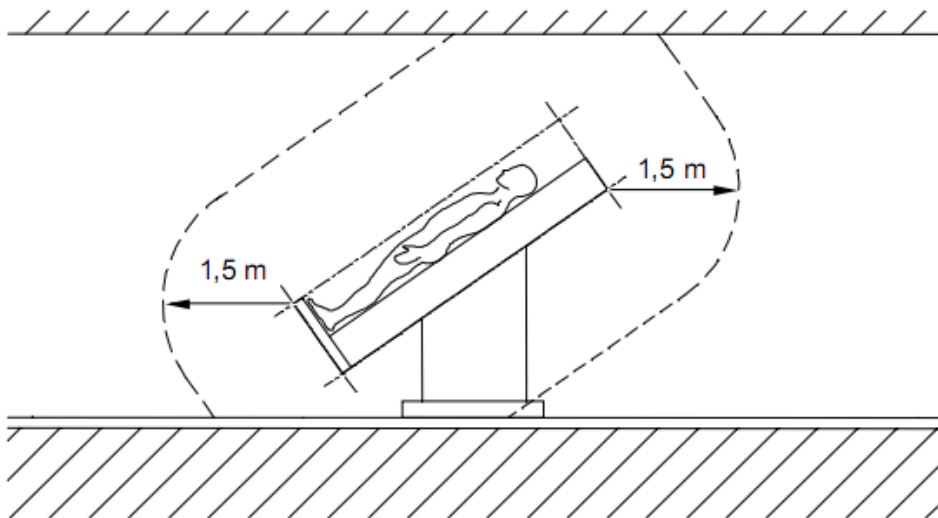
... no medical product in sense of MDD 93/42 EEC by itself

... applicable to be used in ‚patients environment‘ like defined in IEC 60601-1



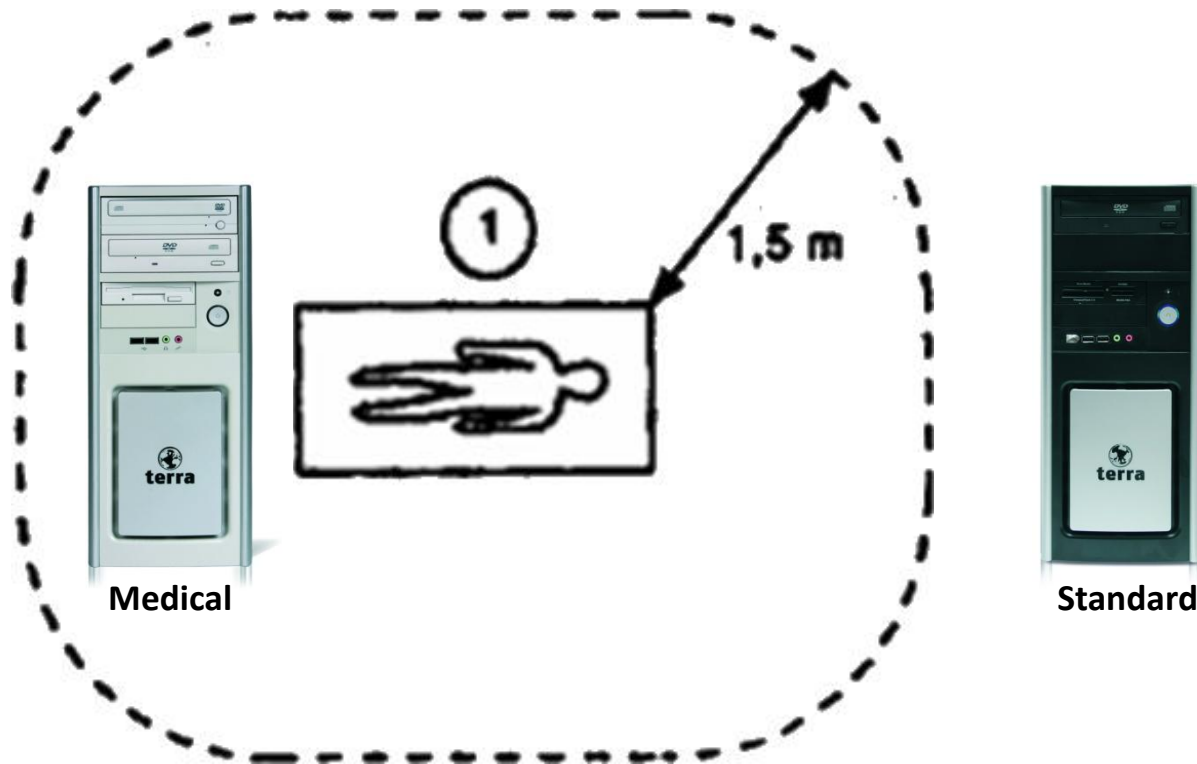
The ‚Patient Environment‘

The ‚Patient Environment‘ is defined in IEC 60601-1:2006 Subclause 3.79



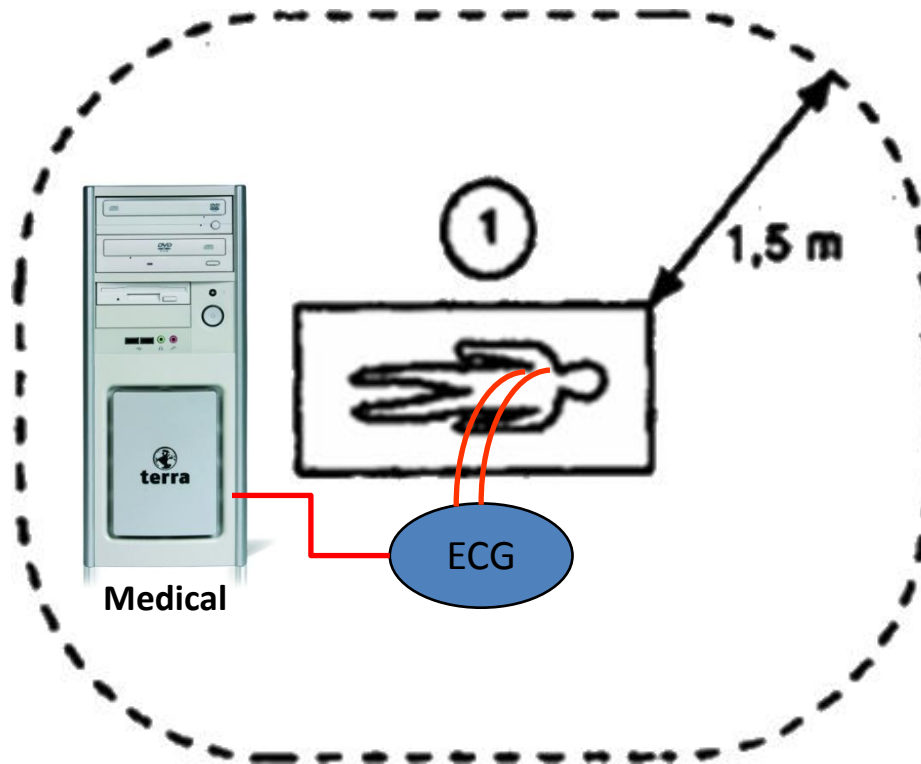
Source: DIN EN 60601-1 3rd Edition

The ‚Patient Environment‘



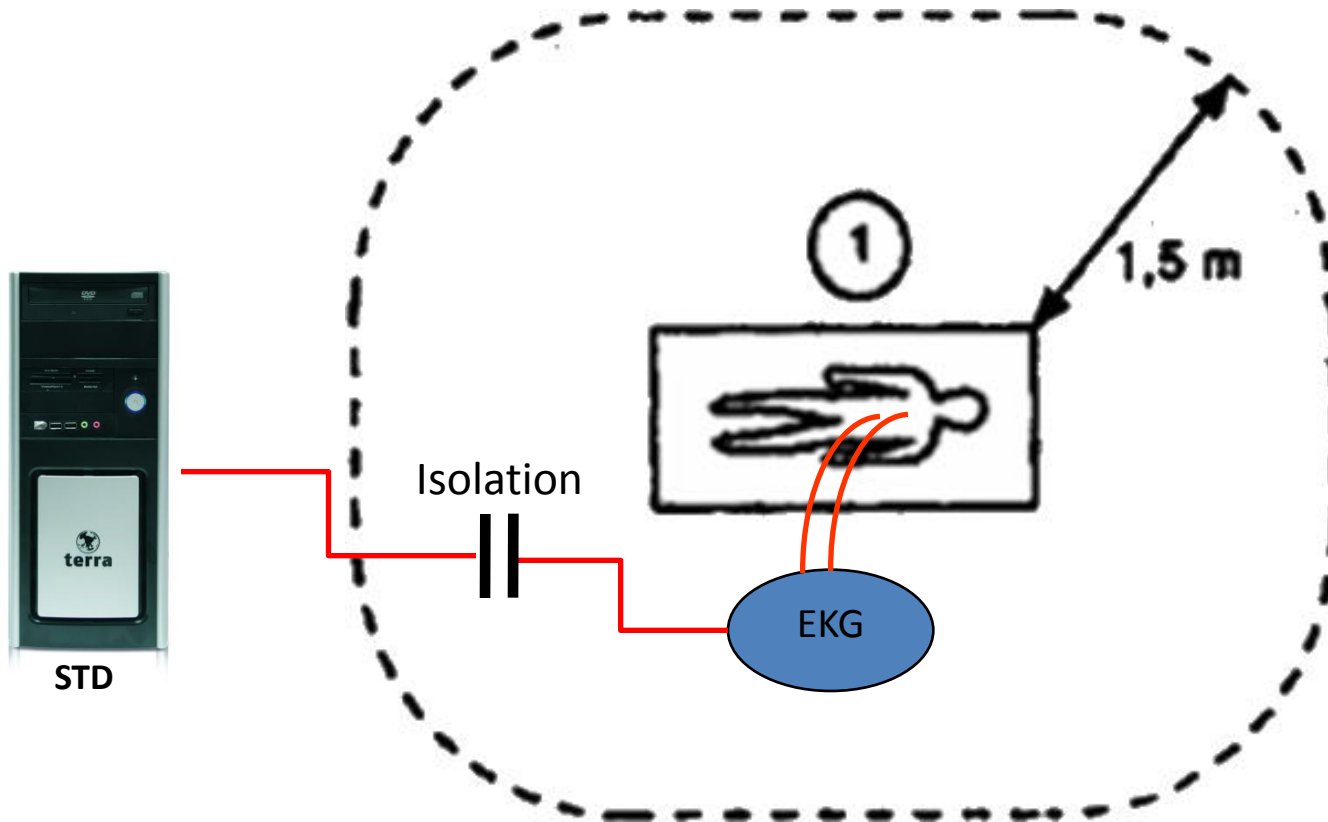
Source: DIN EN 60601-1 3rd Edition

The ‚Patient Environment‘



Source: DIN EN 60601-1 3rd Edition

The ‚Patient Environment‘

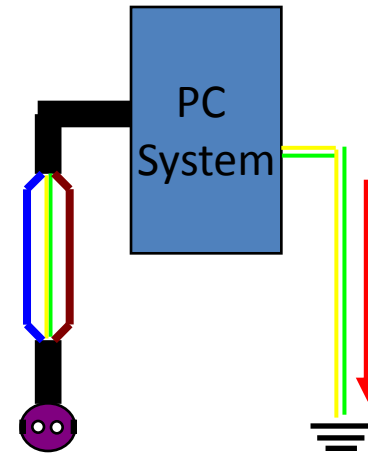


Quelle: DIN EN 60601-1 3rd Edition

The Leakage Current

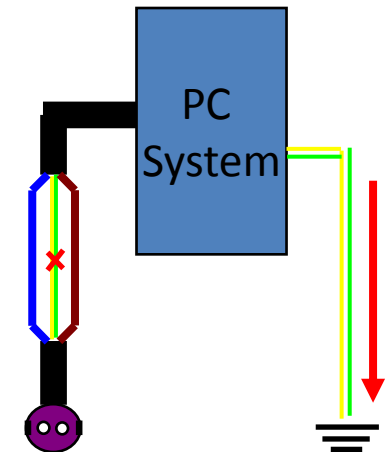
Normal Condition

NC



Single Fault Condition
(Protective Earth broken)

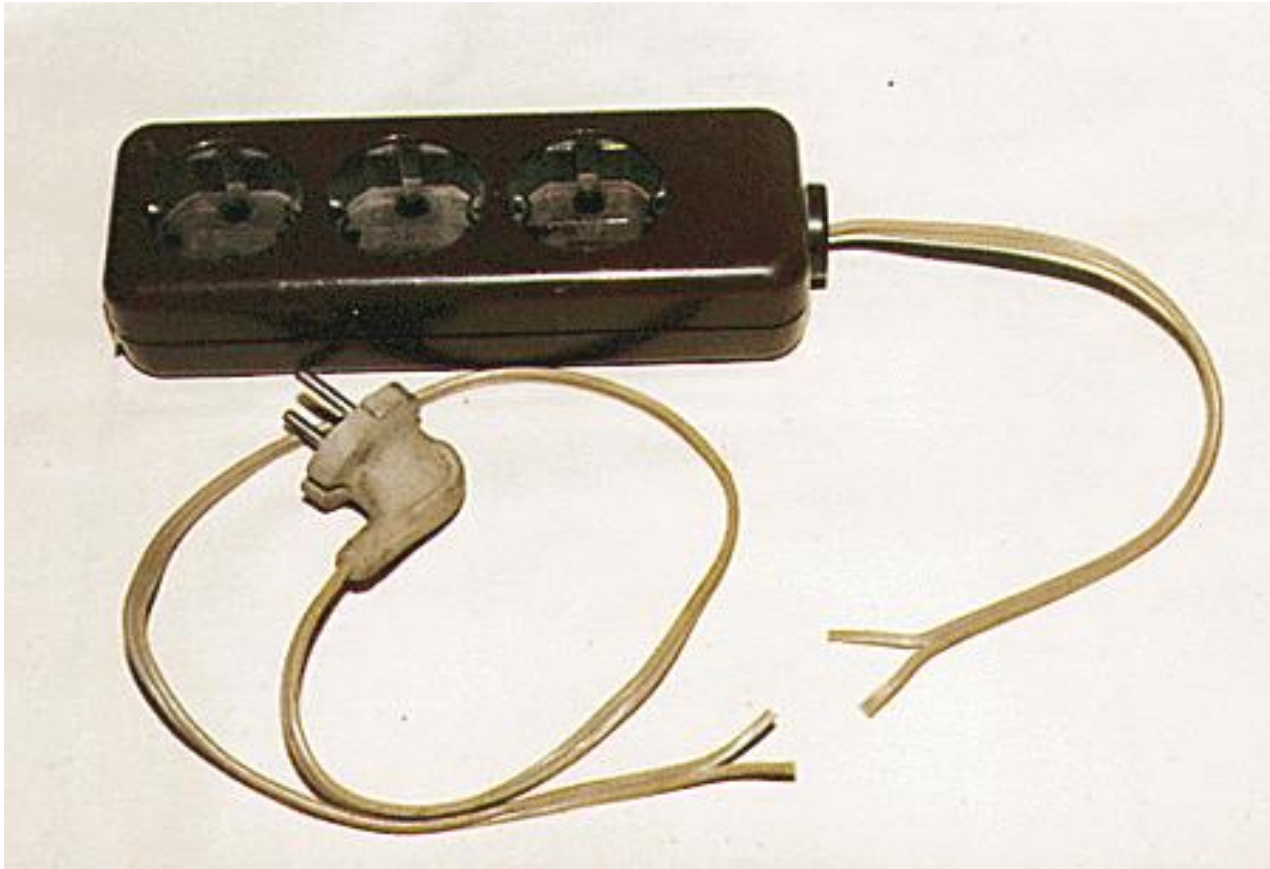
SFC



Example for missing protective Ground

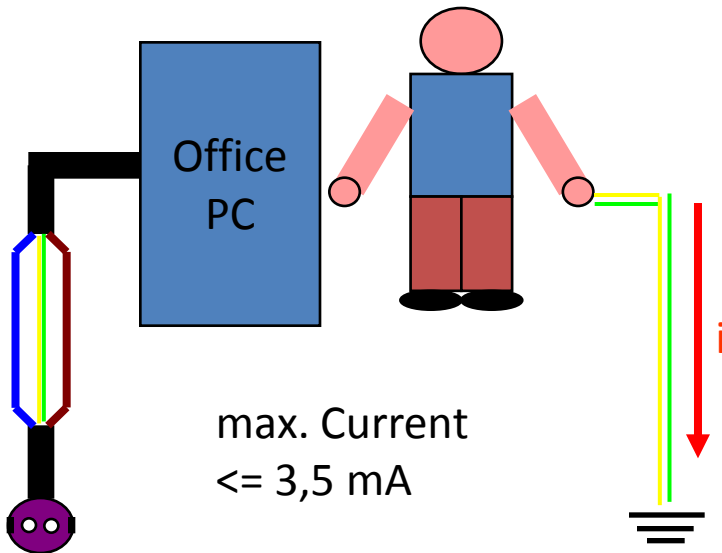


Example for missing protective ground

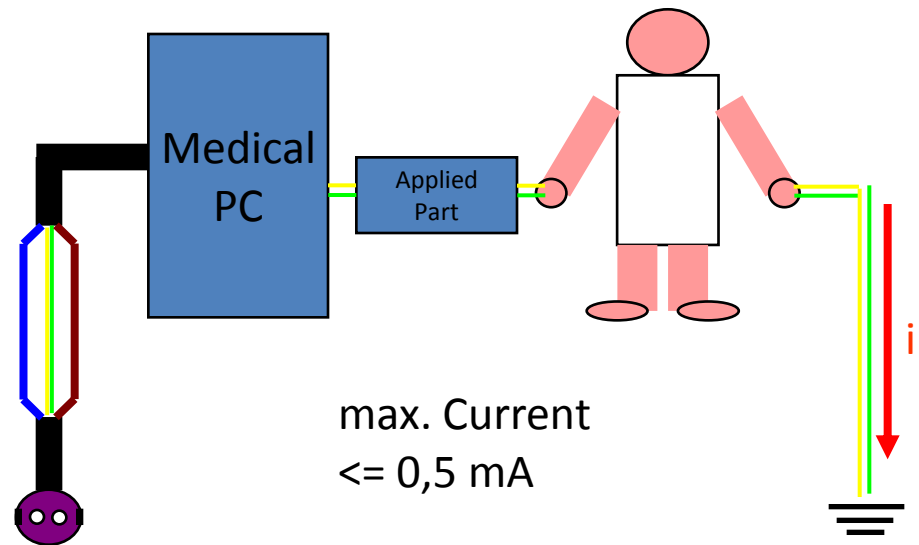


Leakage Current in normal case (NC)

1.

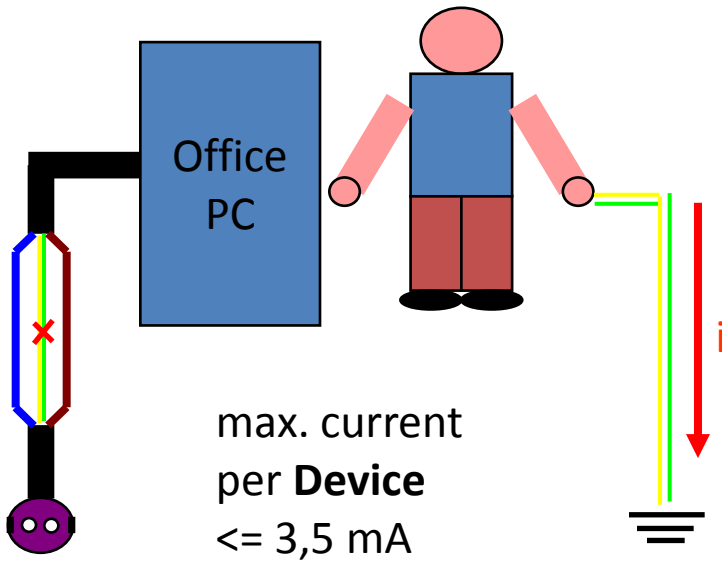


2.

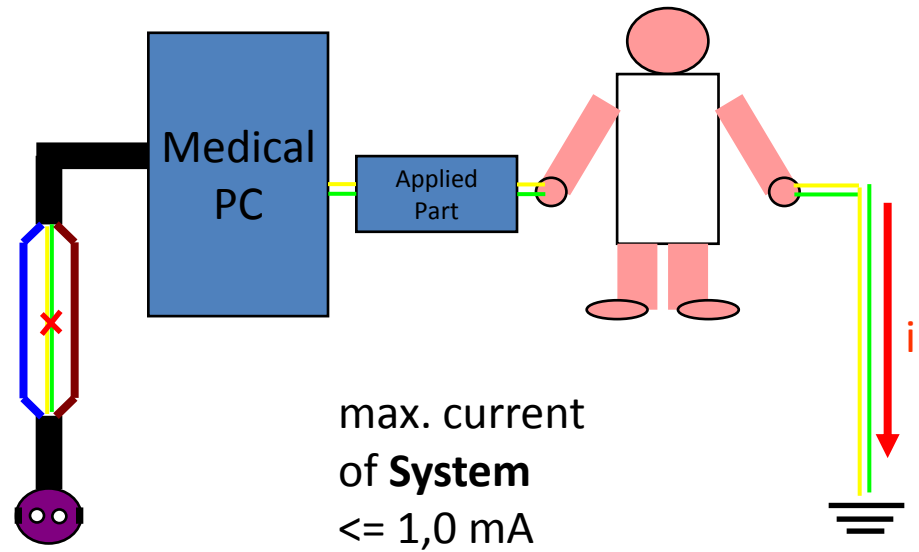


Leakage current in single fault condition (SFC)

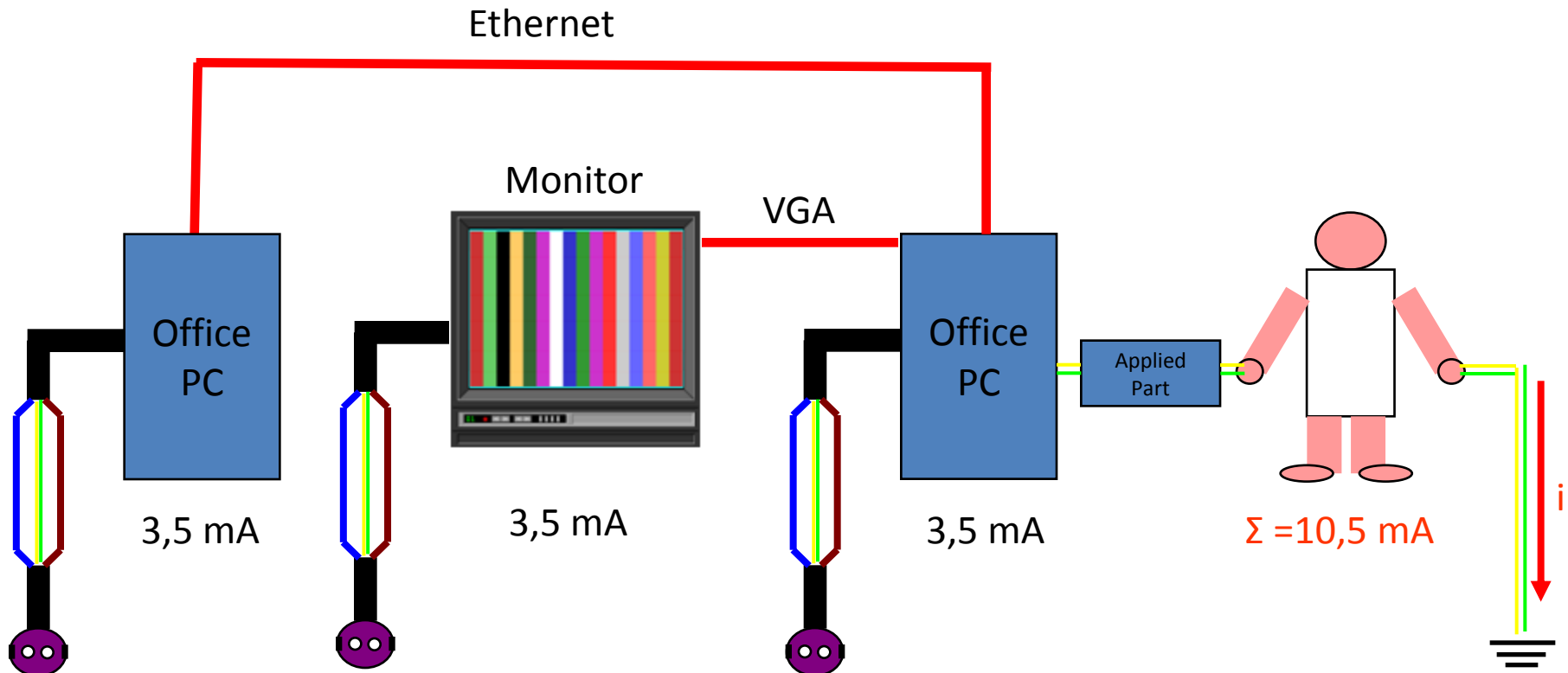
1.



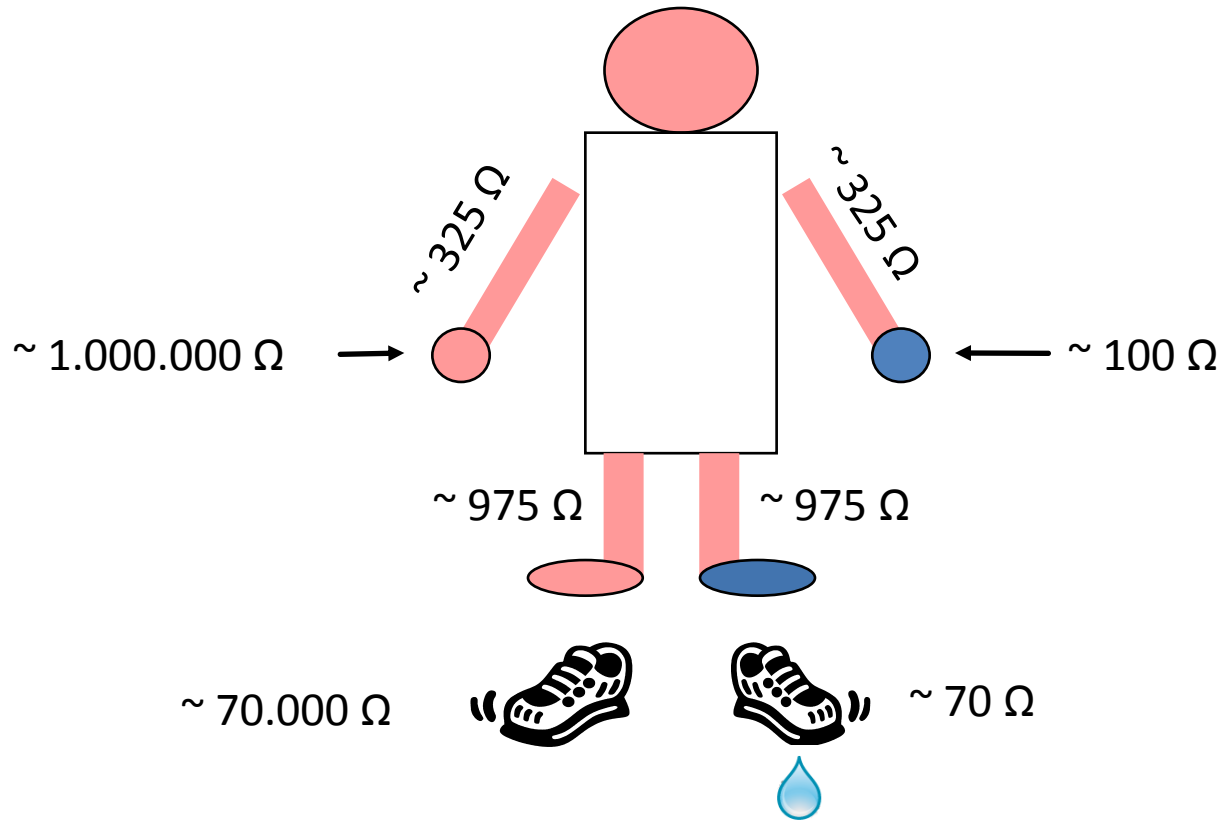
2.



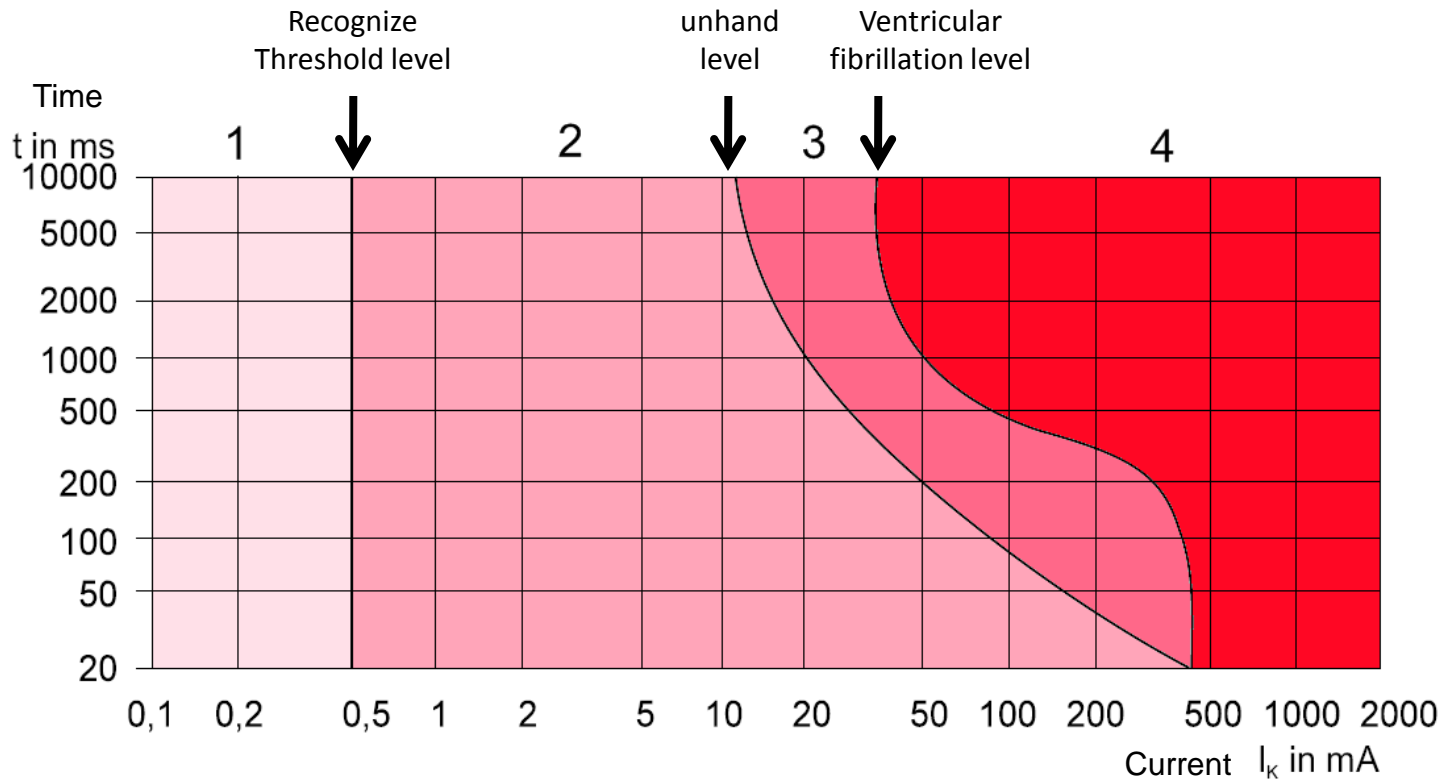
Example: Medical electrical system (MES)



Resistance of the human body



Threshold levels for current conduction



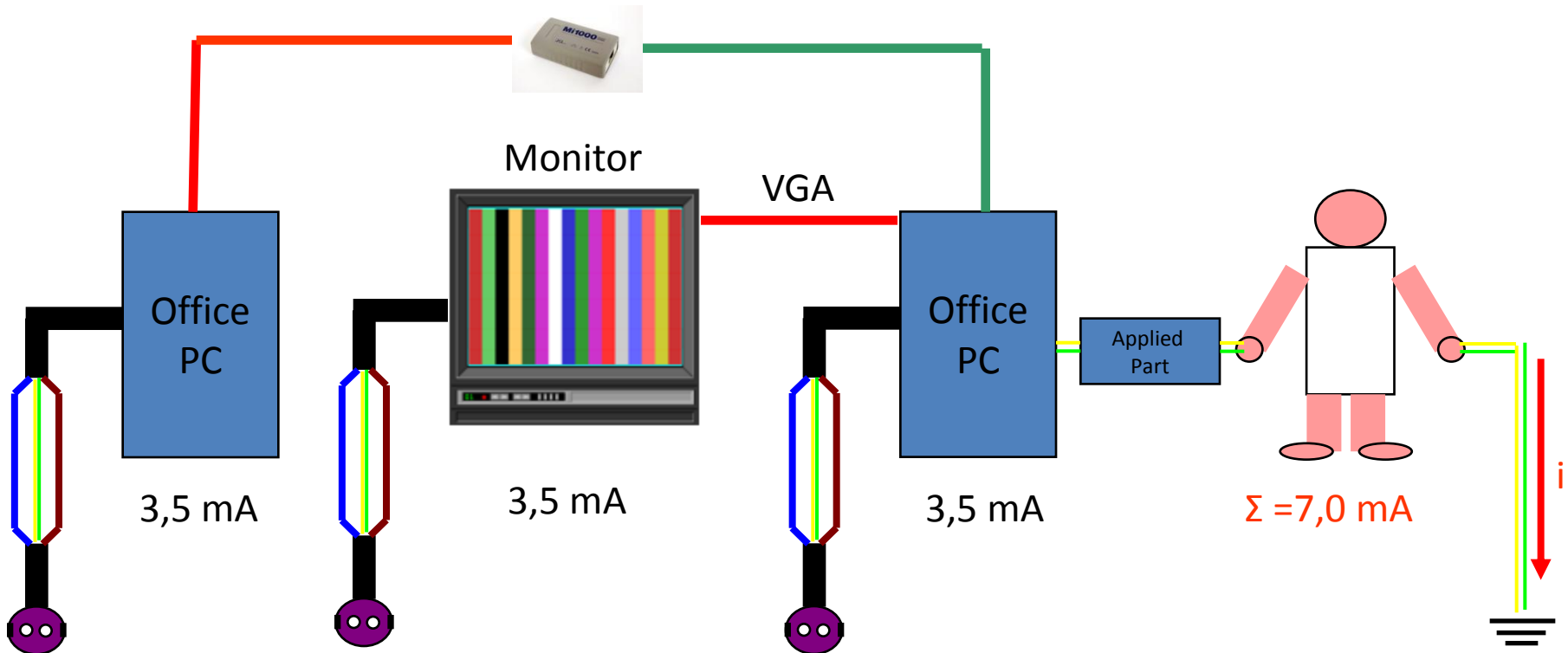
Example for the current conduction between hand and both feet for an adult person. The unhand level will be reached after a conduction Period of 10 seconds at 11 mA.

Example: Stress ECG with bicycle ergometer



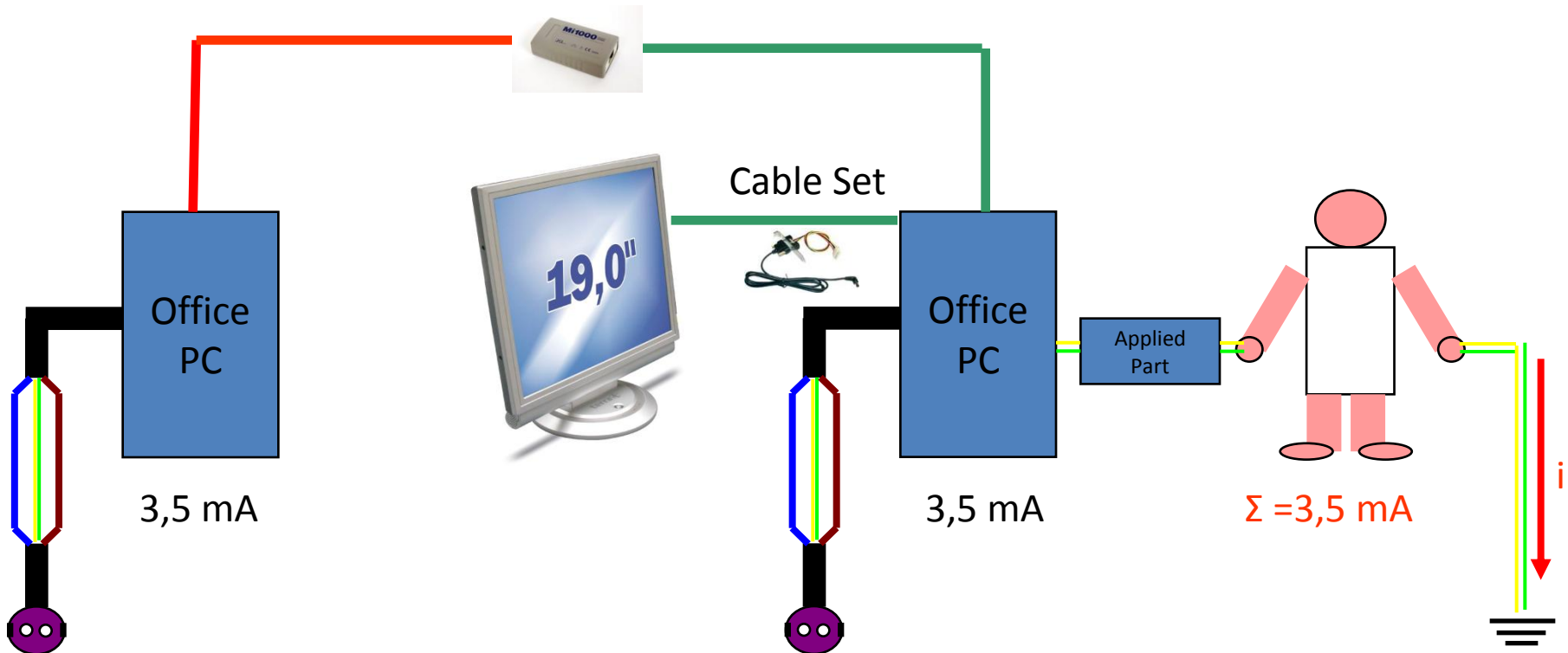
MES: Reducing current with Ethernet Isolation

Ethernet Isolation



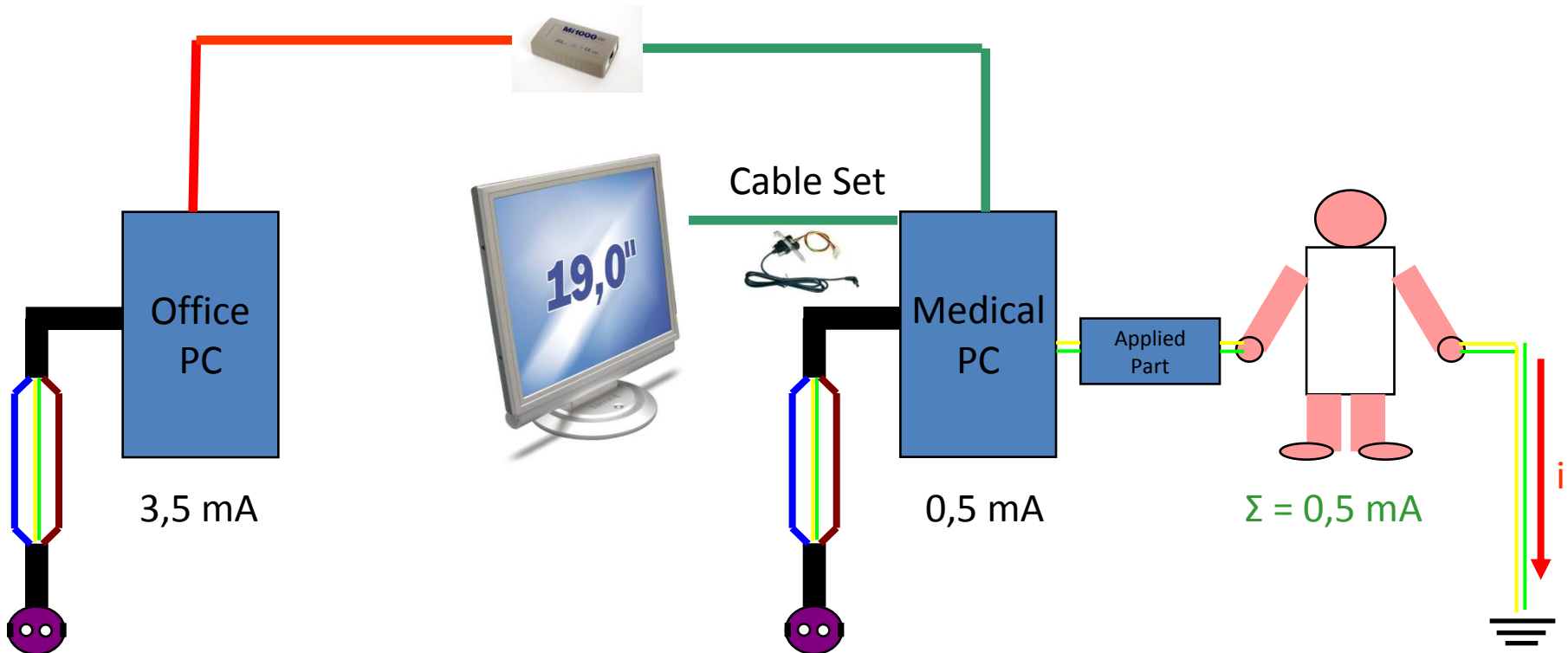
MES: Reducing Current with Monitor Power Set

Ehernet Isolation

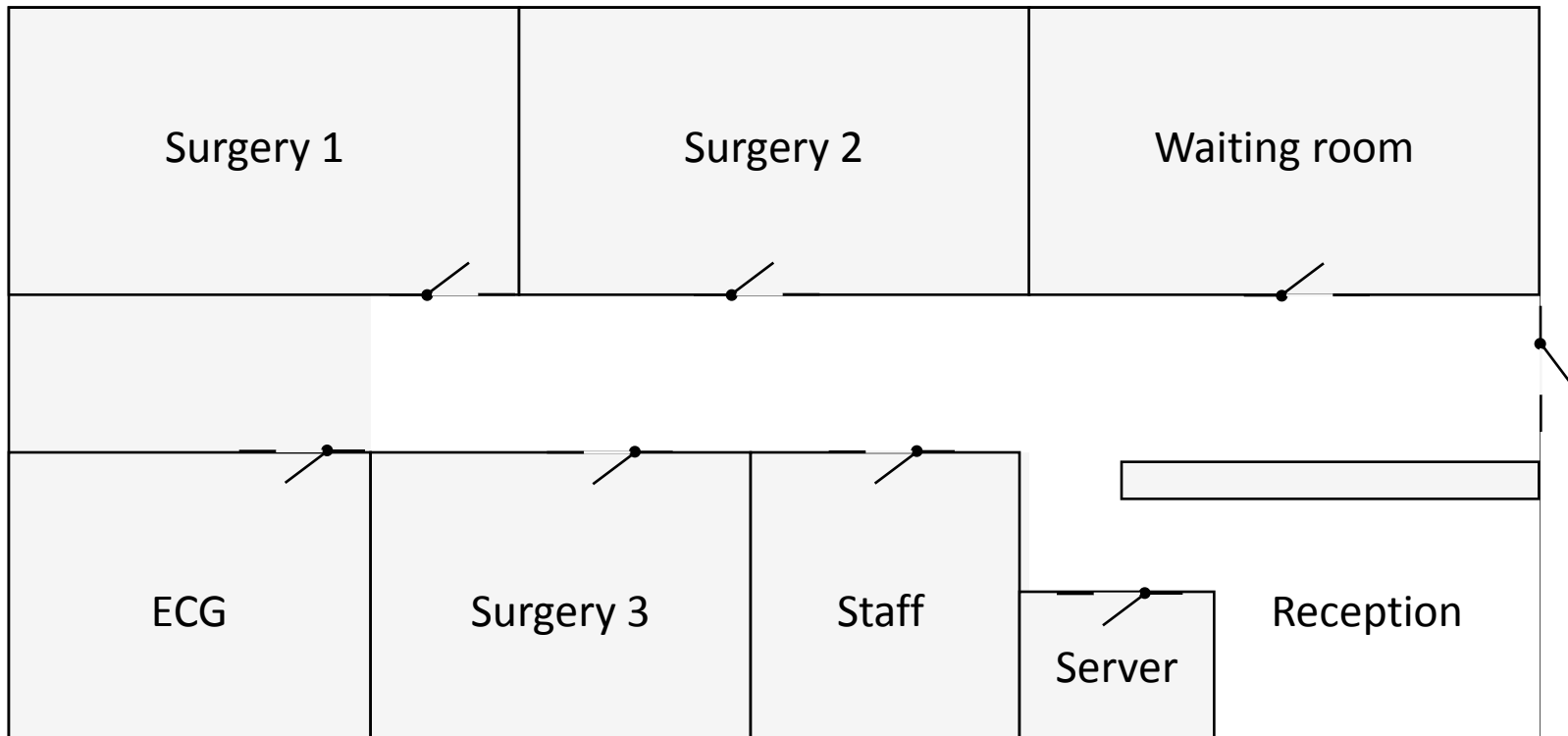


MES: Reducing Current using a Medical PC

Ethernet Isolator



Case study based on a room plan



How to tell the electrician?

The operator of a medical surgery has to ensure, that the electrical installation fulfills the requirements.

The electricians have to be informed about the intended use of the several rooms.

Medical used area:

Area used for the purpose of diagnosis, medical care (including cosmetical care) and observation of Patients.

Group 0:

- Power supply can break down
- Medical care can be interrupted
- No applied parts

Group 1:

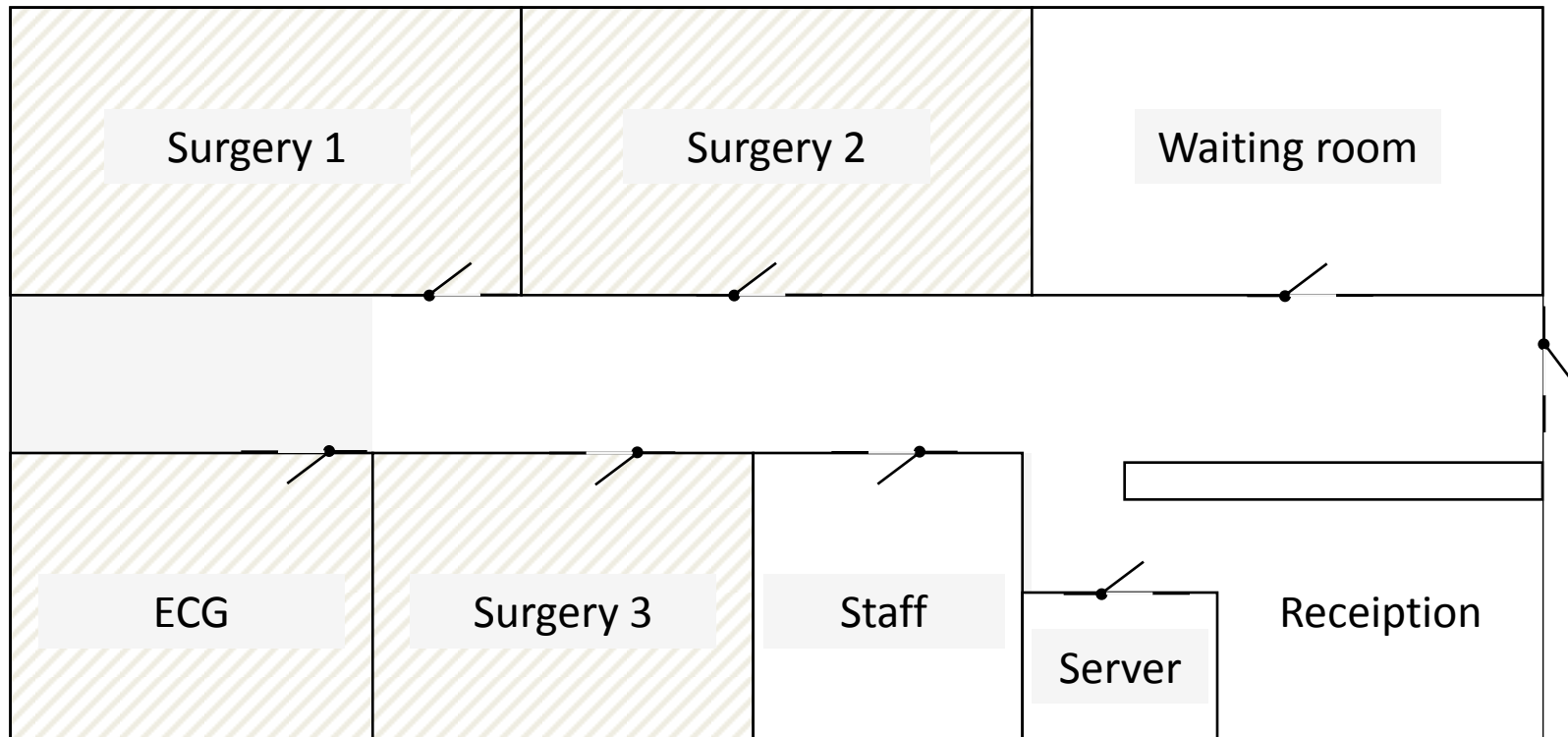
- Power supply can break down
- Medical care can be repeated
- Skin contact and invasive applied parts

Group 2:

- Power supply shall not break down
- Medical care can not be repeated
- Intercardial applied parts

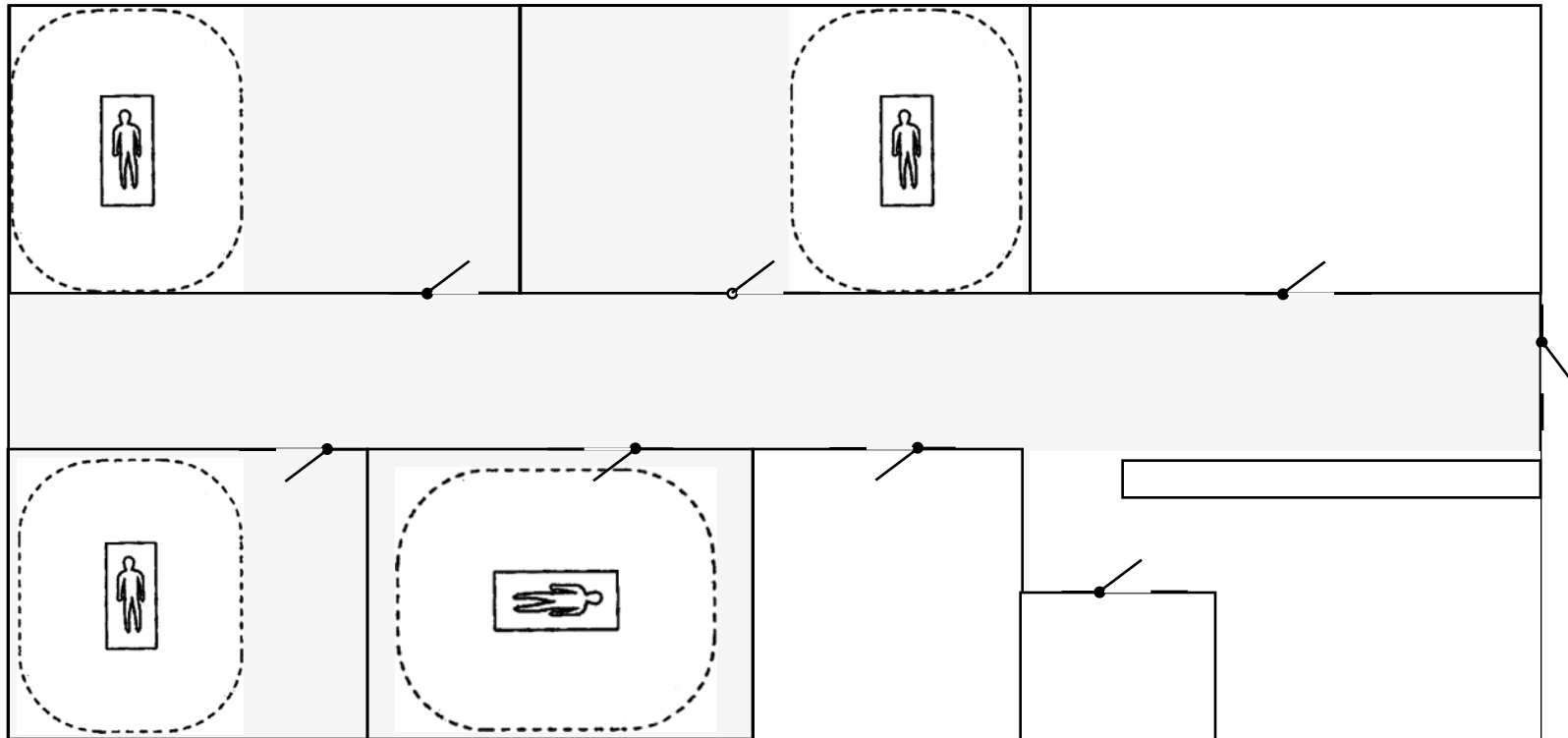
	0	1	2
1 Massage room	x	x	
2 Beds room		x	
3 Birth room		x	
4 ECG, EFG, EHG room		x	
5 Endoscopy room		x	
6 Investigation and medical care room		x	
7 Urology room		x	
8 Xray diagnostic and medical care, except under point 21		x	
9 Hydrotherapy-Room		x	
10 Physiotherapy-Room		x	
11 Anesthesia room			x
12 Operating Theatre / room			x
13 Operation preparation		x	x
14 Operation plaster room		x	x
15 Anesthetic recovery room		x	x
16 Intercardiac catheter room			x
17 Intensive care room			x
18 Angiography room			x
19 Hemodialysis room		x	
20 MRT room		x	
21 Nuclear medicine Room		x	
22 Premature infants room			x

Case study based on a room plan

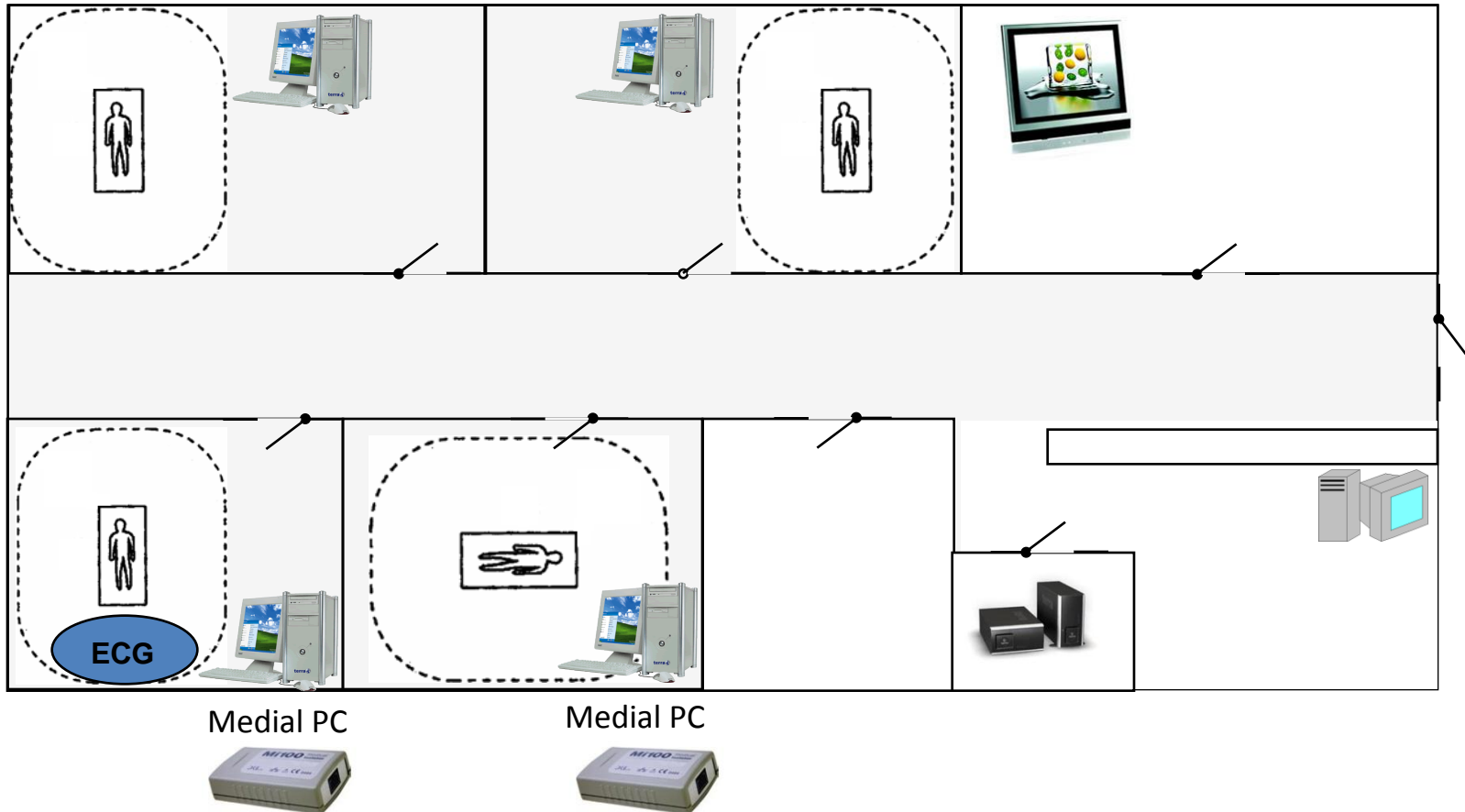


Basic: VDE 100 Part 710 (German directive) Medical used area

Room plan: Patient Environment



Room plan: Computer and IT devices



Baaske Datentechnik e.K. products

Product Group Ethernet



MI 1005 Medical Isolator 5kV

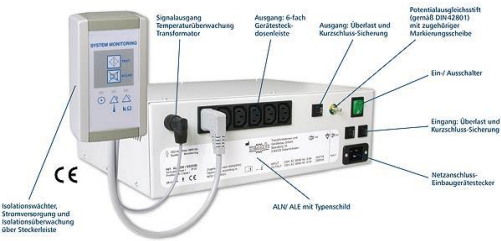
The MI 1005 network isolation module is suitable for the use in 10/100/1000-BaseT-Ethernet Gigabit networks with full IEEE 802.3 compatibility and no restrictions in the maximum cable length. If PCs or other electrical devices are connected to an Ethernet network in the patient's environment inadmissible leakage currents can appear from other devices that are also connected to network. The MI 1005 blocks these currents and voltages up to 5.000V over the copper network.

The MI 1005 device has been tested according to IEC 60601-1 and IEC 60601-1-2 in an accredited laboratory of a notified body with certificate.

More information on www.baaske.net

Baaske Datentechnik e.K. products

Product Group Power Supply



Medical Grade Isolation Transformers

Special one or three phases transformer for medical use and power supply in medical environment. These devices have been developed for strict requirements to the leakage current in medical purpose.



Medical Desktop Adapters 20/50/120W

These devices provide electric units with external power supply like for example printers, tft displays and usb peripherals. At a rating from 20 to 120 Watts they are available in voltages from 5/9/12/13/15/22/24 V.



Power Cable for Devices 1mm²

Compared to generic power lead cables for household use these cables are supplied with a bigger lead cross section. The Lead cross section of normal power cables has a cross section of 0,75mm². This special power cable has a cross section of 1mm², other sizes like 1,5mm² are also available on request, depending on the required quantity.

More information on www.baaske.net

Baaske Datentechnik e.K. products

Product Group Interfaces



USB Isolator STD 1.5 LWL

The USB Isolator targets low-cost end user applications. It provides all the flexibility of extended range USB in a ready-to-use package.

The USB Isolator extends the range of USB up to 40 m/131 ft over fiber optic cable. Fiber-optic transmission provides exceptional reliability and immunity to interference including complete electrical isolation between computer and device. The USB Isolator is available in lengths of 10, 20, 30 and 40 meters for extension/isolation, and in a 1 m length for use in applications where electrical isolation is desired.



RS232 Isolator STD LWL

The principle of the RS232 Isolation is based on the conversion from copper to light signals by converting them to fibre glass and back. This is the solution for protecting the serial port against high voltages or lightning strike. These devices are equipped with a patent-registered adapter plug which allows a cable length of up to 100m. Simply a sharp edged tool is required to configure the required cable length. The configured cables can easily be plugged into the converters.

More Information on www.baaske.net

Baaske Datentechnik e.K. products

Product Group Medical PC



Medical PC Systems and Computers

'Medical PC' is a commercial made up word and describes computers and laptops, that fulfill the general requirements for basic safety and essential performance, as described in IEC 60601-1. They also meet the EMC limits, which are described in DIN EN 60601-1-2. But after all, they are no medical products for the purpose of the "Medical Device Directive" 93/42 EWG. These computers are designed to be used in the patient environment with no physical contact to the patient. You can find more information about the patient environment and the rules and definitions for the leakage current in our [Download](#) area.

More Information on www.baaske.net

Medical Information Technology

Information for manufacturers, resellers and users

**Thank you very much for
your interest!**

