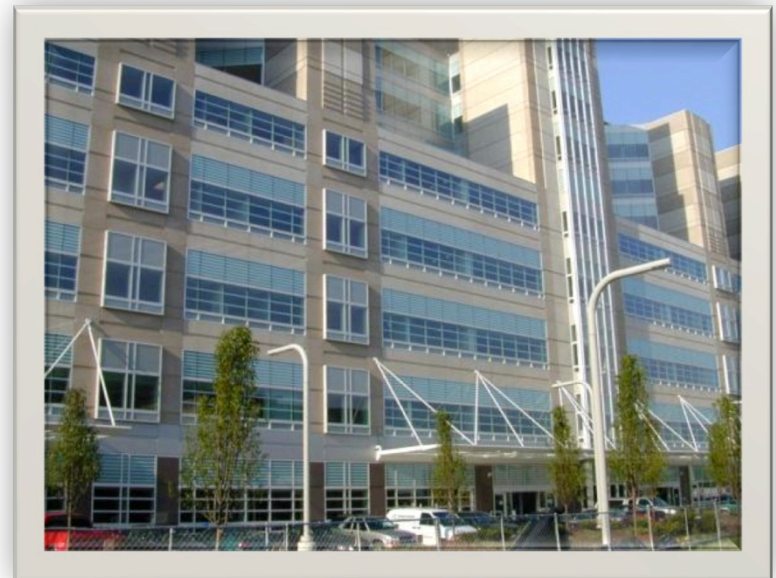


POWER IN ELECTRICAL SAFETY

Electrical Safety in Medical Locations –
with a view on the draft of European
standard prHD 60364-7-710

*Presentation by
Wolfgang Hofheinz,
Bender Group, Germany*

*Paris, France
31 Mai 2011
11:30 am*



Dipl.-Ing. Wolfgang Hofheinz

CTO, Dipl.-Ing. W. Bender GmbH & Co. KG

Vice President, Bender Group

President of DKE- Deutsche Kommission Elektrotechnik Elektronik
Informationstechnologie im DIN und VDE

(the German Standard Organisation responsible for electrotechnical standards)

- *Convenor of CLC TC64 WG 10*
- *Involved in CLC TC64 WG 6*
- *Convenor of IEC TC85 WG 8*
- *Convenor and member of several German standard committees*

ELECTRICAL SAFETY



No Medical Location can afford to be without it!

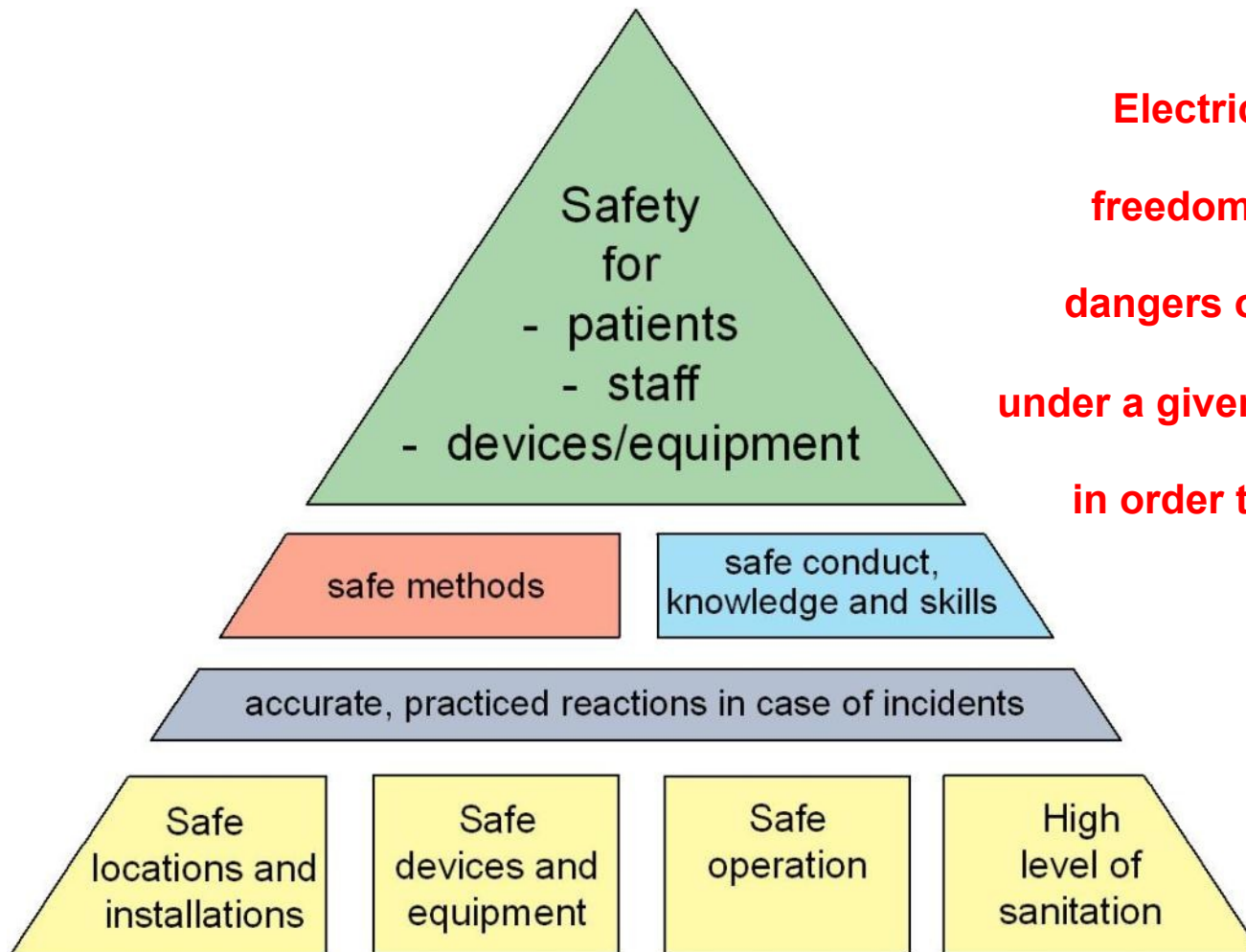
Reasons for electrical safety requirements



Conditions to be considered:

- the electrical resistance of the skin may be reduced through the insertion of catheters;
- body functions may be taken-over by apparatus, e.g. during surgery;
- natural reaction may be reduced through analgesia or switched-off when anaesthetized.
- The heart muscle is highly sensitive to electric currents (currents $>10\mu\text{A}$).
- Fire and explosion risks through use of anesthetics, disinfectants or cleaning agents.

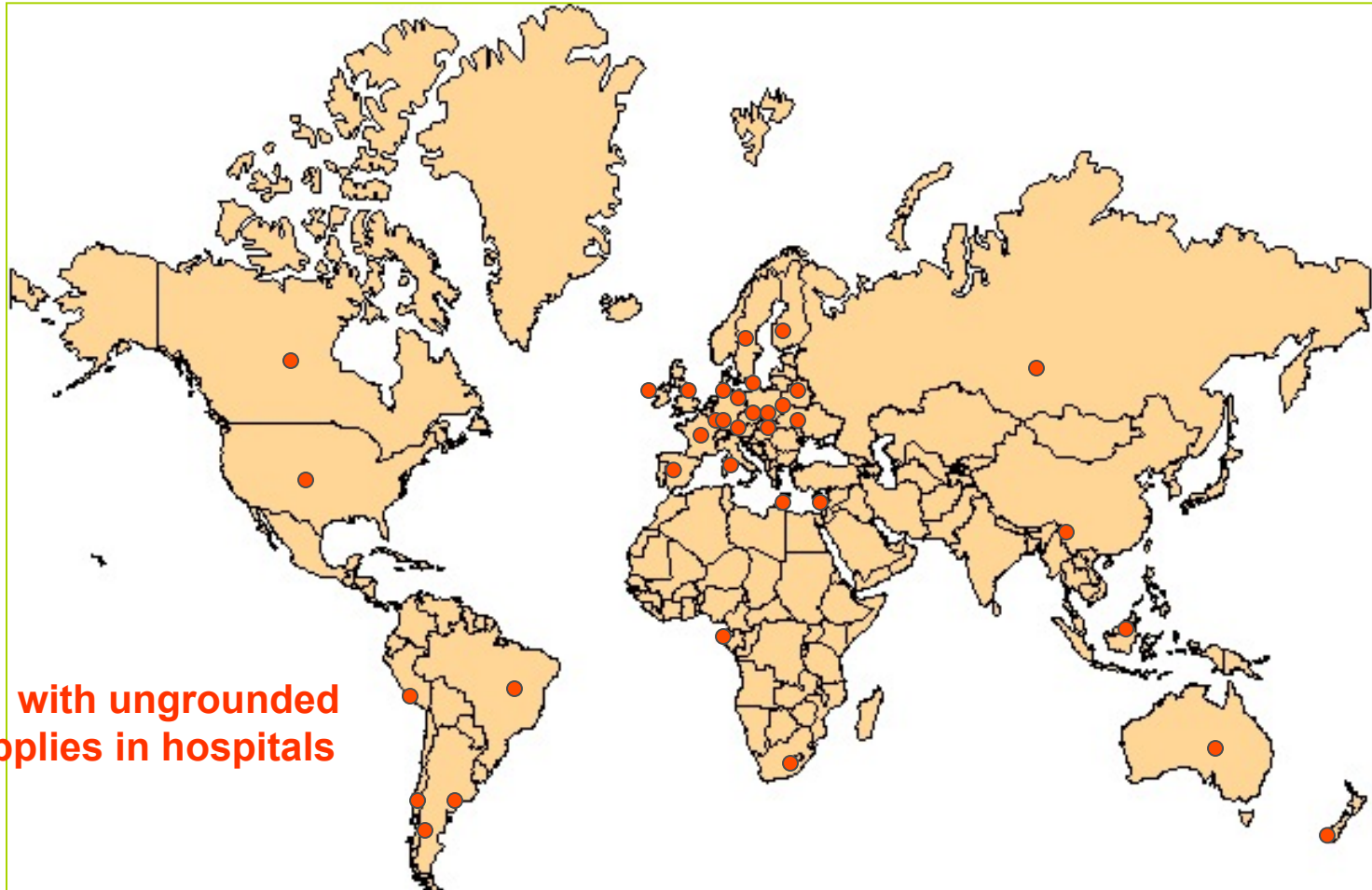
The safety concept in healthcare facilities



Electrical safety means freedom from most of the dangers of electrical current under a given set of *circumstances* in order to *minimizing risks*.

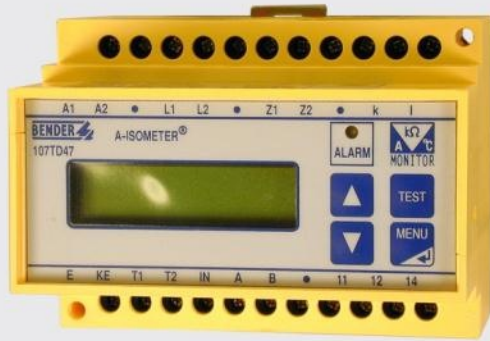
World-Wide Application of Unearthed Power Supply (Medical IT System)

Countries with ungrounded power supplies in hospitals



In the US, the Medical IT System is called Isolated Power System.

Monitoring of unearthed power supply systems (medical IT systems)

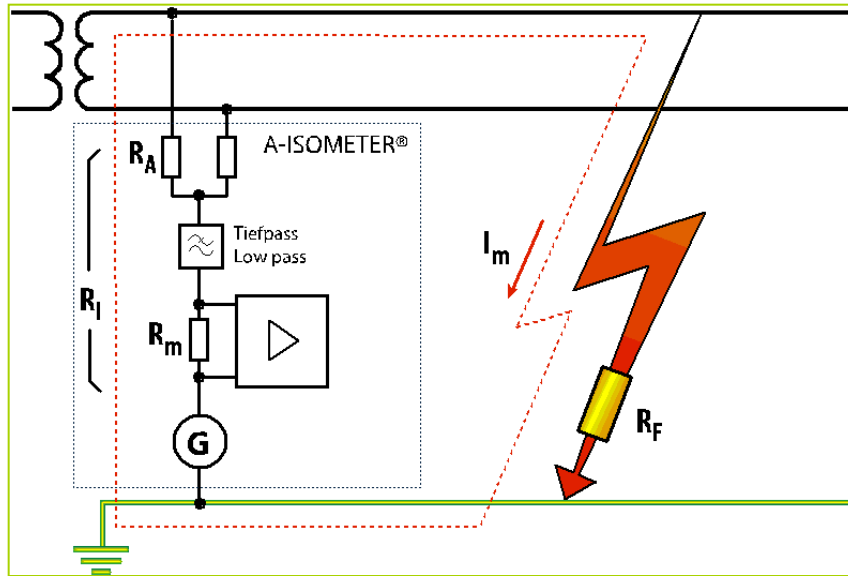


- IMD Monitoring
- Resistive fault detection and location



- LIM Monitoring
- Prospective leakage current and fault location

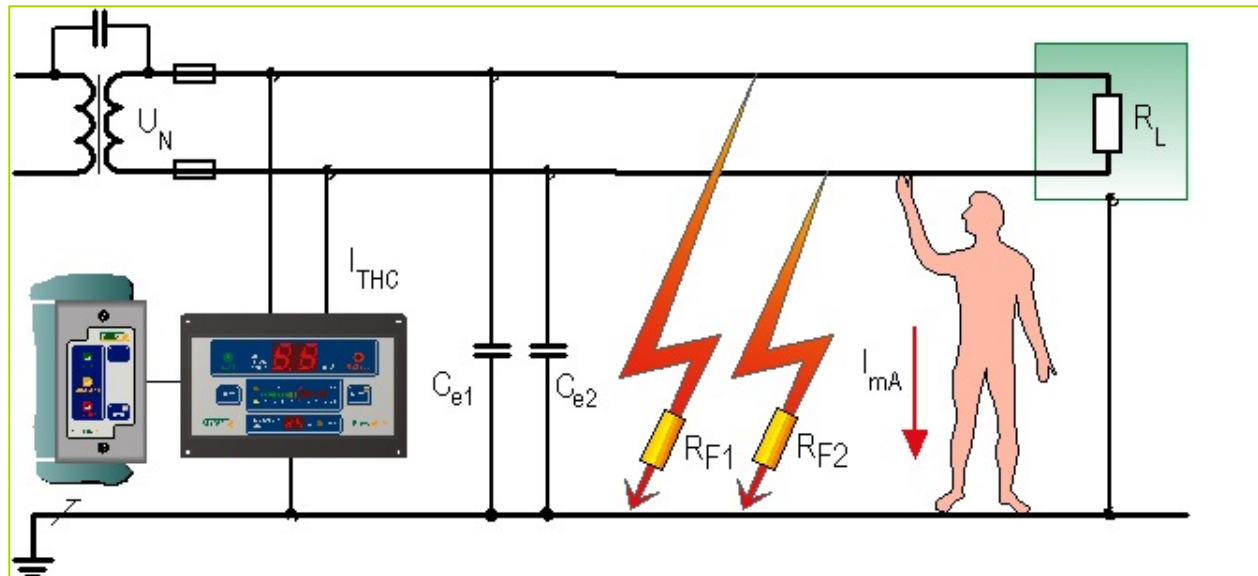
Monitoring Unearthed Power Supply (Medical IT system) with IMD



with
Insulation Monitoring Device (IMD)

- **IMD** connected between the phase conductors and earth.
- **Measuring voltages U_m** generated by G is superimposed on the system via the coupling R_i , the measuring resistance R_m and a filter.
- An **insulation fault R_F** between system and earth closes the measuring circuit, **measuring current I_m** is flowing.
- I_m causes a **voltage drop U_m** proportional to the insulation fault R_F at the measuring resistance R_m .
- Display indicates the **ohmic insulation resistance**.

Monitoring Unearthed Power Supply (Medical IT System) with LIM



- **LIM monitors impedance** of the unearthed power supply
- Display indicates the **total hazard current in mA**

Electrical Safety

according to

IEC 60364-7-710:2002-11

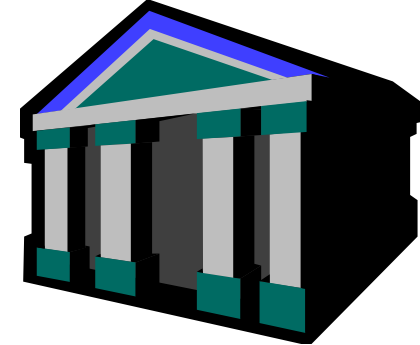
for

- Hospitals
- Private Clinics
- Medical and Dental Practices
- Health Care Centres
- Dedicated Medical Rooms



Classification of Medical Locations Established in Agreement With:

- **the medical staff**
- **health organization concerned**
- **Legal body responsible for work safety in accordance with national regulations**



Classification Of Medical Locations

HD 60364-7-710:2002 classifies medical locations in three groups:

Group 0 medical location;

Group 1 medical location;

Group 2 medical location.

Classification of a medical location are related to:

- **the type of contact between applied parts and the patient,**
- **and the purpose for which the location is used.**

Classification of the Group 0, 1 and 2 Medical Locations

Classification Group	0	1	2
Disconnection in case of the first fault a) Patients at risk b) Can the examination or treatment be repeated or interrupted ?	no yes	no yes	yes no
Failure of the normal power supply a) Patients at risk b) Can the examination or treatment be repeated or interrupted ?	no yes	no yes	yes no
Use of applied parts a) Externally or invasively, but not for intracardiac application and where power failure can cause danger to life. b) For intracardiac procedures in operating theatres and for vital treatment where discontinuity of the supply can cause danger to life.	no no	yes no	yes yes

Examples for Allocation of Medical Locations

Medical location	Group			Class	
	0	1	2	≤0,5 s	>0,5 s ≤15 s
1. Massage room	X	X			X
2. Bedrooms		X			
3. Delivery room		X		X ^a	X
4. ECG, EEG, EHG room		X			X
5. Endoscopic room		X ^b			X ^b
6. Examination or treatment room		X			X
7. Urology room		X ^b			X ^b
8. Radiological diagnostic and therapy room, other than mentioned under 21		X			X
9. Hydrotherapy room		X			X
10. Physiotherapy room		X			X
11. Anaesthetic room			X	X ^a	X
12. Operating theatre			X	X ^a	X
13. Operating preparation room		X	X	X ^a	X
14. Operating plaster room		X	X	X ^a	X
15. Operating recovery room		X	X	X ^a	X
16. Heart catheterization room			X	X ^a	X
17. Intensive care room			X	X ^a	X
18. Angiographic examination room			X	X ^a	X
19. Haemodialysis room		X			X
20. Magnetic resonance imaging (MRI) room		X			X
21. Nuclear medicine		X			X
22. Premature baby room			X	X ^a	X

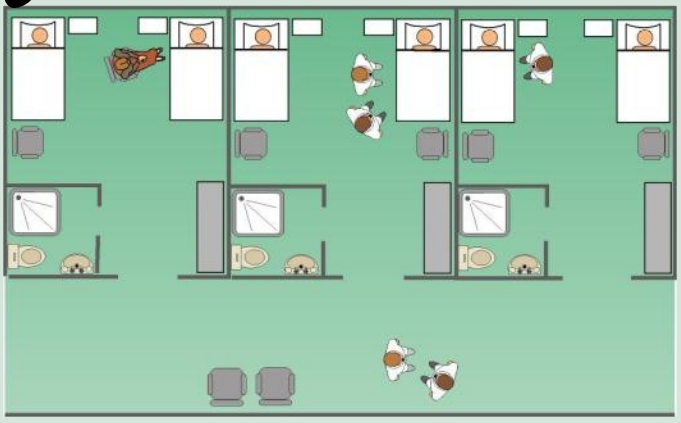
^a Luminaires and life-support medical electrical equipment which needs power supply within 0,5 s or less.
^b Not being an operating theatre.

Groups of Medical Locations

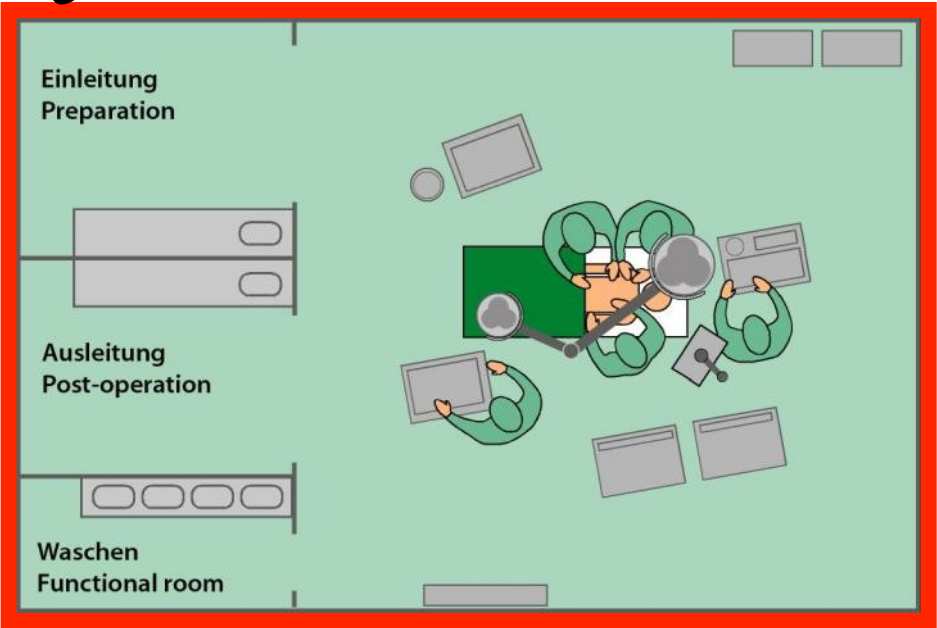
Group 0



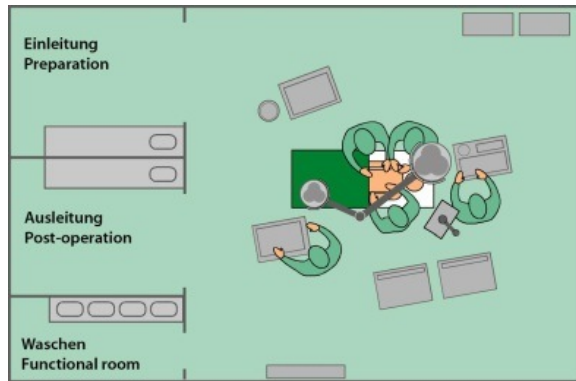
Group 1



Group 2



The electrical installation of medical locations of Group 2



The Medical IT-System

HD 60364-7-710, 710.413.1.5)

- In Group 2 medical locations, the medical IT system shall be used for circuits supplying
 - medical electrical equipment
 - systems intended for life support
 - surgical applications
 - other electrical equipment located in the "patient environment",
 - excluded equipment listed in 713.413.1.3.



Transformers for Medical IT Systems

(710.512.1.1)

- Transformers shall be
 - installed in close **proximity** to, inside or outside, the medical location
 - placed in cabinets or enclosures to **prevent unintentional contact with live parts**.

- Rated voltage U_n on the secondary side of transformers ≤ 250 V a.c.

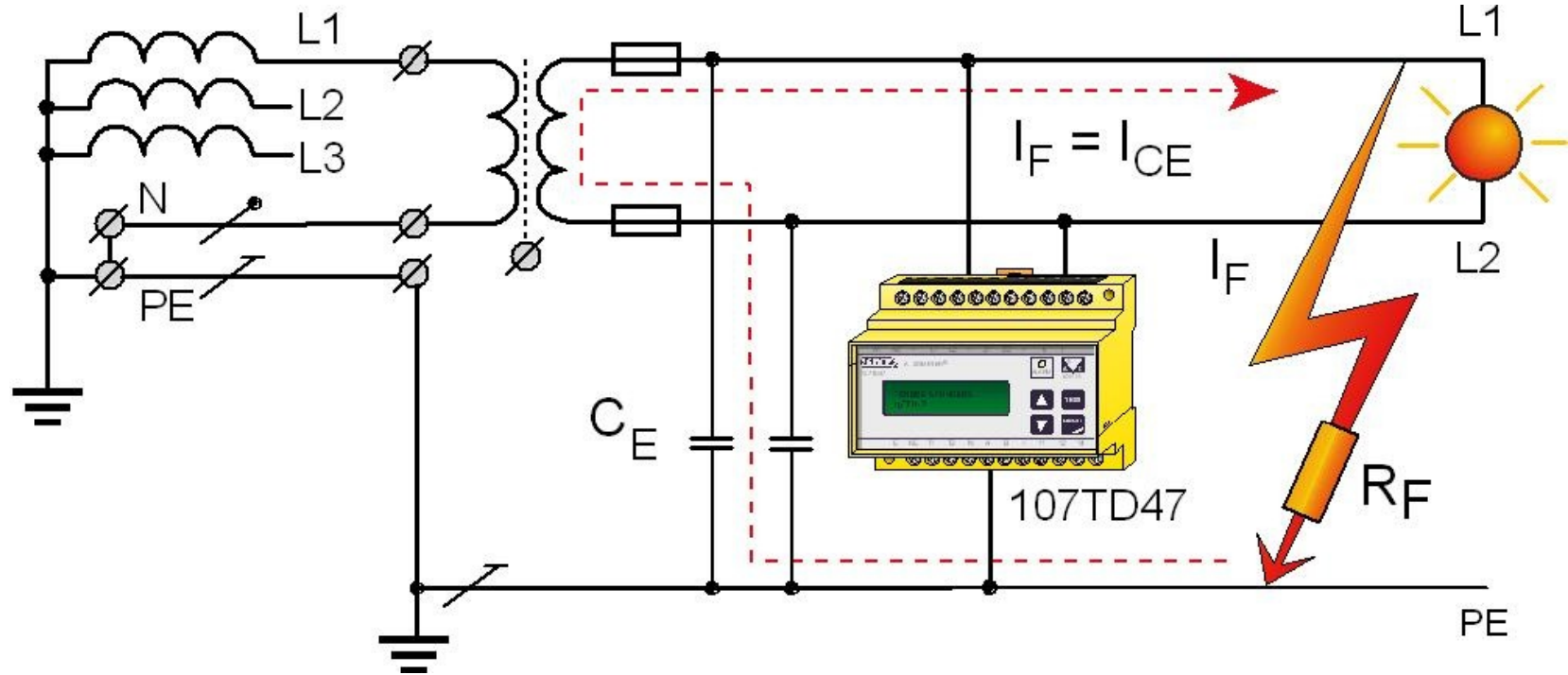
- Transformers according IEC 61558-2-15, with additional requirements:
 - The **leakage current** of the output winding to earth and the leakage current of the enclosure, when measured in no-load condition and the transformer supplied at rated voltage and rated frequency, ≤ 0.5 mA.
 - The **rated output** of the single-phase transformers 0.5 kVA ... 10 kVA.
 - For three-phase loads with an IT system a **separate three-phase transformer** shall be provided for this purpose with output line-to-line voltage not exceeding 250 V.

Transformers for Medical IT Systems

- Single phase transformers
 - ES0107 series
 - acc. to IEC 61558-2-15
 - 0,5...10 kVA
 - Vertical or horizontal version,
 - or installed in an enclosure



Insulation Monitoring in Medical IT Systems



- Only the insulation monitoring device (IMD)
 - signals the **first fault**
 - provides **advance information** for the user

The Insulation Monitoring Device (IMD)

The medical IT system shall be **equipped with an insulation monitoring device** in accordance with Standard EN 61557-8:2007 with the following specific requirements:

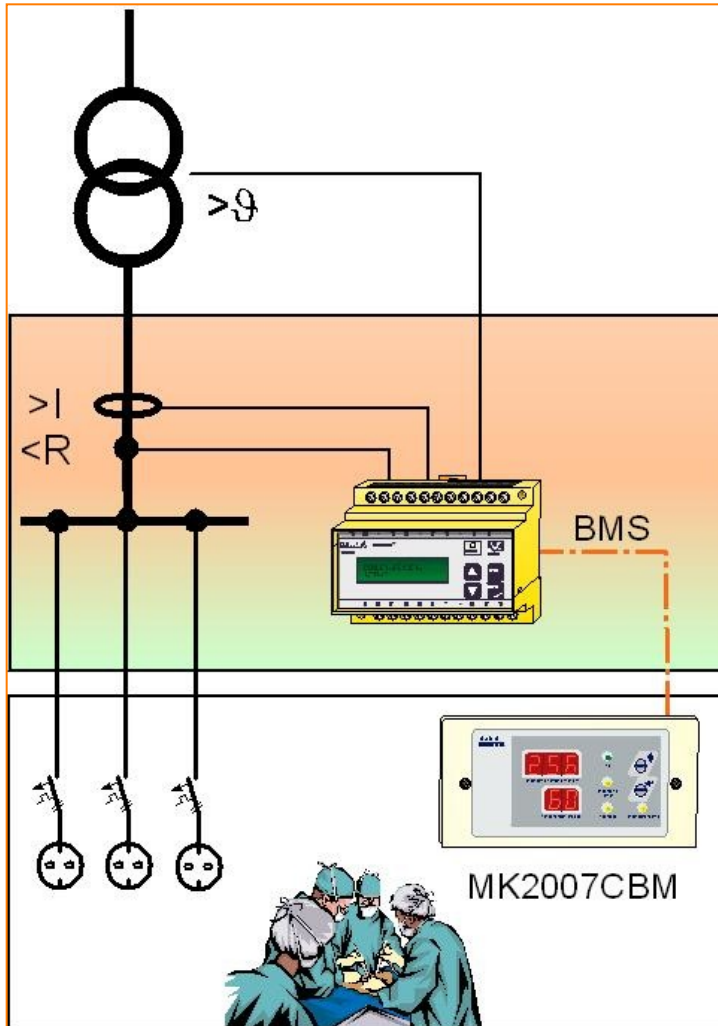
- AC internal impedance $\geq 100 \text{ k}\Omega$
- test voltage $\leq 25 \text{ V DC}$
- injected current $\leq 1 \text{ mA peak}$, even under fault conditions
- indication when insulation resistance $\leq 50 \text{ k}\Omega$
- test device shall be provided

Protection of the IT System Against Dangerous Overload

- Monitoring of overload and high temperature for the medical IT transformer is required ...
- but no circuitbreaker for protection against overload and overcurrent should be used (risk: unexpected tripping of the fuse)
- Overcurrent protective devices (MCB) should only be used for short-circuit protection.
- If too many medical electrical devices are in use in an operating room, the information will be displayed on a remote indicator.



Load, Temperature and Insulation Monitoring



with an IMD of type 107TD47

Remote Alarm Indications in Rooms of Group 2 Medical Locations



Each medical IT system, shall have
an
**acoustic and visual alarm
system**

at a
suitable place so that it can be

permanently monitored

by the medical staff.

Remote Alarm Indications

A green signal lamp to indicate normal operation

- A yellow signal lamp which lights when the minimum value set for the insulation resistance is reached. It shall not be possible for this light to be cancelled or disconnected.
- The yellow signal shall go out on removal of the fault and when the normal condition is restored.
- An audible alarm which sounds when the minimum value set for the insulation resistance is reached. This audible alarm may be silenced.
- Note: Additionally overload and overtemperature of the medical IT system transformer must be indicated.



Complex Task: Insulation Fault Location



The Problems:

▪ **Socket-outlets**

- In intensive care locations **many socket outlets** are arranged at every patient place,
 - Accordingly in a 4 bed-intensive care unit, e.g. they could be quite numerous.
- Hence, if a defective device causes an insulation fault, it might be difficult to locate the associated socket outlet, the defective device is connected to.

▪ **Expert knowledge**

- Medical staff in intensive care units usually often **lack the technical know-how.**

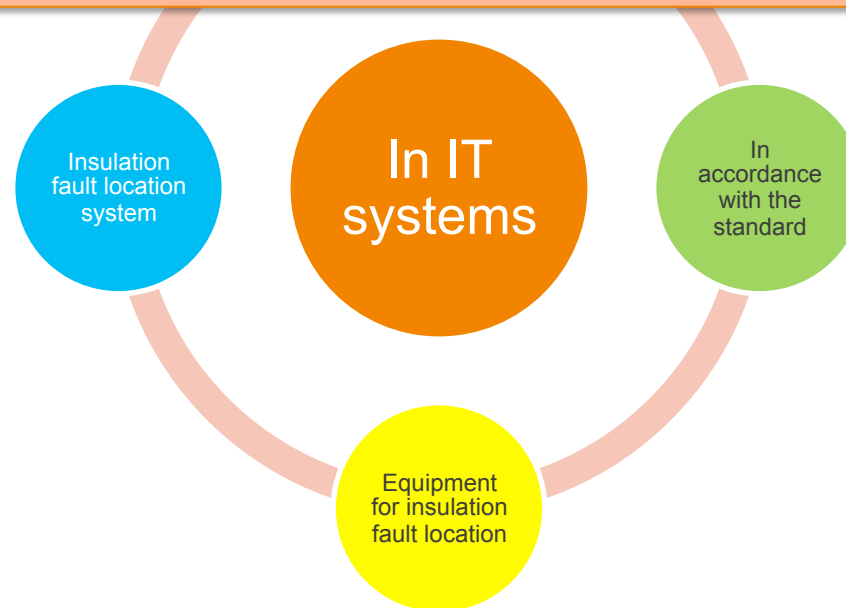
▪ **Insulation faults**

- In order to guarantee the safety for the patient, it is imperative that the insulation fault is located quickly.

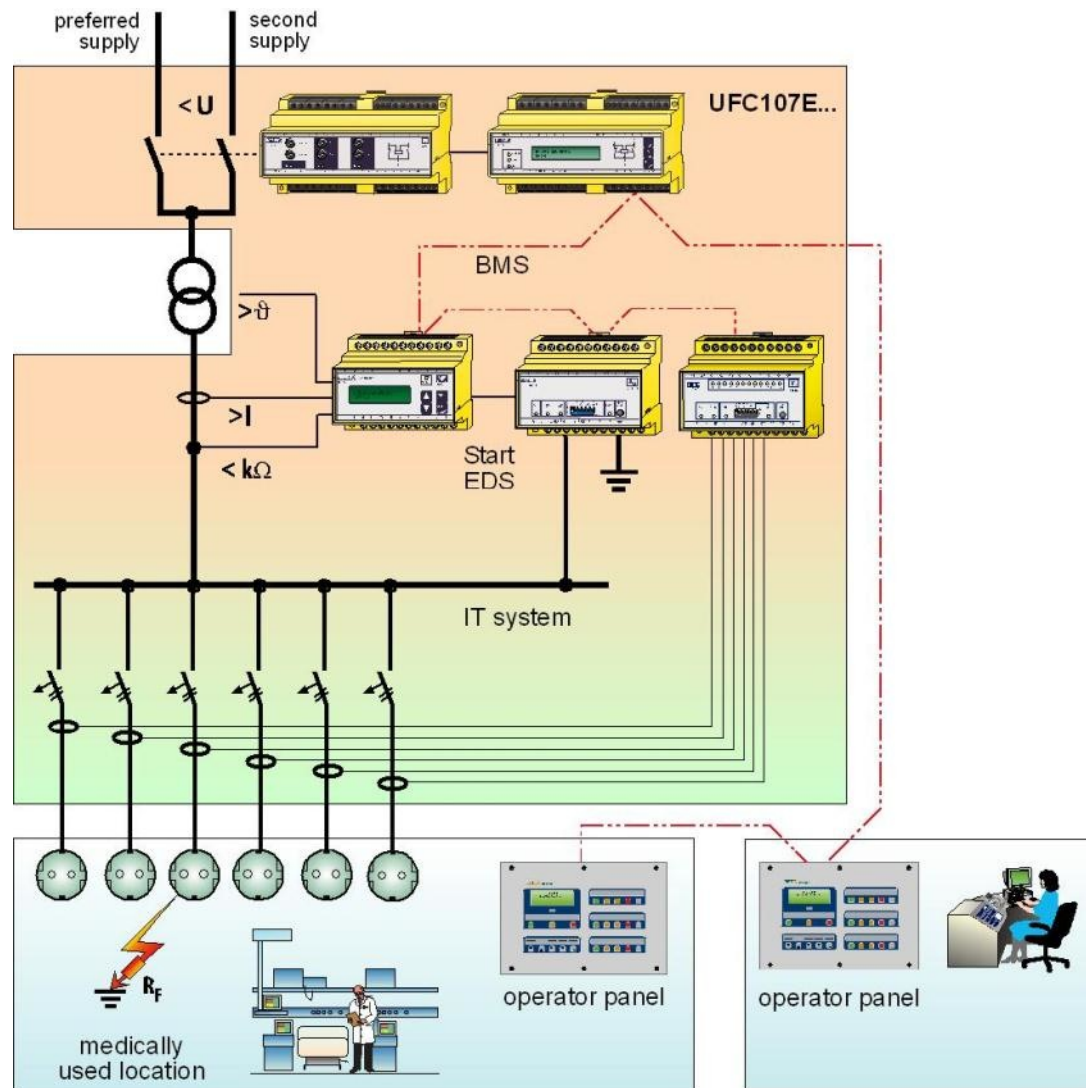
Electrical safety in low voltage distribution systems – Equipment for testing, measuring or monitoring of protective measures –

Part 9: Equipment for insulation fault location in IT systems

Edition 2.0:2009



Design of an Insulation Fault Location System



To Summarize

Unearthed Power Systems (medical IT systems) mean:

- Added safety at no additional cost.
- No power interruption at first fault.
- Early warning of faulty medical equipment.
- Visual and audible signals if there are hazardous situations.
- Low leakage current to ground.
- Low touch voltage in case of an insulation fault.



I would like to thank you for your attention and will now be happy to answer any questions you may have!

- **Dipl.-Ing. W. Bender GmbH & Co.KG**
Londorfer Strasse 65
35305 Gruenberg
Germany

- Dipl.-Ing. Wolfgang Hofheinz - CTO
 - Phone +49 (0) 6401 807-120
 - Fax +49 (0) 6401 807-109
 - E-Mail Wolfgang.Hofheinz@bender-de.com

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