

Safety power supply in medical group 2 locations acc. to IEC364—7-710 (NEK 400-5-56) – Norwegian projects



Welcome and contact

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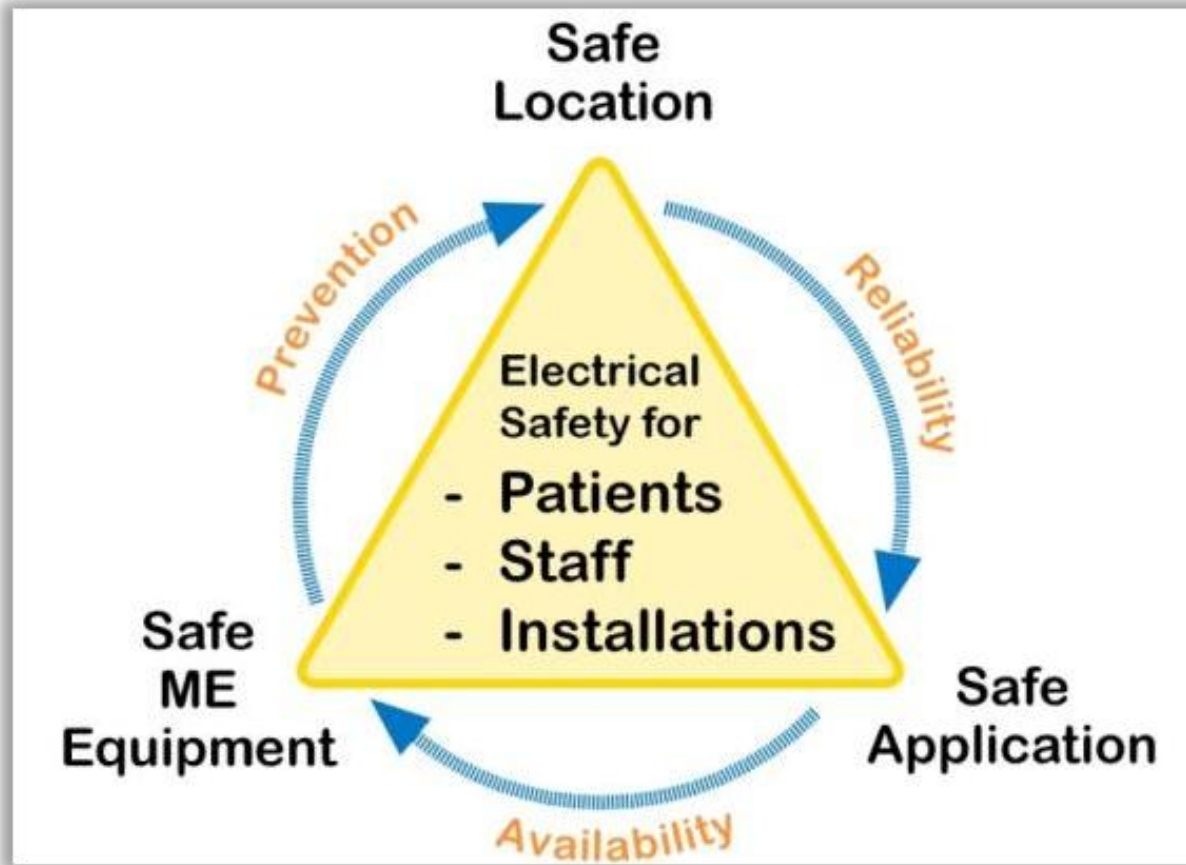
www.elteco.no



Why electrical safety?



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no medical location can afford to be without it!

The risks for the patients in hospitals ...

- The patient's natural reactions to hazards are reduced or switched-off
- The heart muscle is highly sensitive to electric currents (currents $> 10 \mu\text{A}$)
- The insertion of catheters and the like into the body may reduce the electrical resistance of the skin
- Body functions are temporarily or continuously supported or substituted by medical electrical devices
- Fire and explosion risks through the use of anaesthetics, disinfectants or cleaning



- Even small currents flowing through the human body put the **patients life and health at risk !**



- The availability of the power supply must be guaranteed, even under fault conditions!



December 2011

Positive voting result for FprHD 60364-7-710:2011

VOTING RESULTS - FORMAL VOTE

221_2011-0317

FprHD 60364-7-710:2011 (Third vote) Reference Document : IEC 60364-7-710:2002 (Modified) Title : Low-voltage electrical installations - Part 7-710: Requirements for special installations or locations - Medical locations	Submission : 2011-09-30 Deadline : 2011-12-02 Subsector : W27 Project : 2282 TC(s) : IEC/TC 64 CLC/TC 64 Directive(s) : - Mandated : - Supersedes : -
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Results **Countries** (* = with comments, ** = no answer received at CS)
ACCEPTANCE : AT*,BE,BG,CH,CZ,DE,DK,EE,ES*,FI,FR*,GB,GR,HR,HU,IE,IS,LT,LV,NL,NO,RO,SE,SI
REJECTION : IT*,PL*
Abstention : CY,LU**,MT,PT,SK

Total members/weighted votes
 24 (286)
 2 (56)

Evaluation

Proposed implementation dates

	All countries		EEA countries	
1) Simple majority of members for acceptance (Yes/No)	24/2	YES		
2) Proportion of positive weighted votes ≥ 71%	84	YES		
Conditions fulfilled		YES		

doa : dor + 6 months
 dop : dor + 12 months
 dow : dor + 36 months

Automatic conclusion : To be implemented by all countries

which will lead to EN standard **EN60364-7-710:2011**
(mandatory in EU countries)

- Solutions for electrical safety according to IEC 60364-7-710


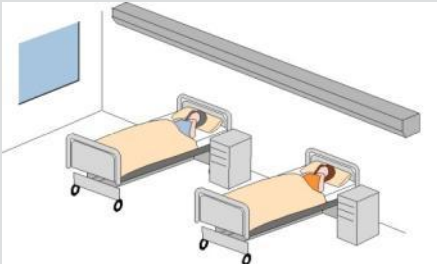
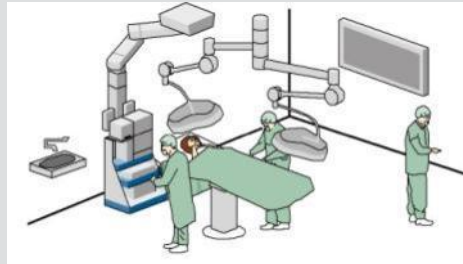


Source: www.trilux.com

Group definitions according IEC 60364-7-710



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	710.3.5 Group 0	710.3.6 Group 1	710.3.7 Group 2
Applied part	Medical location where no Applied parts are intended to be used	Medical location where applied parts are intended to be used as follows: <ul style="list-style-type: none"> Externally Invasively to any part of the body, except where 710.3.7 applies 	Medical location where applied parts are intended to be used in applications such as intra-cardiac procedures, operating theatres and vital treatment.
Power supply	Discontinuity cannot cause danger of life	Discontinuity of electrical supply does not represent a threat to safety of the patient	Discontinuity (failure) of the supply can cause danger of life
Example	<ul style="list-style-type: none"> Massage room Office 	<ul style="list-style-type: none"> Bedroom Haemodialysis room Physiotherapy room 	<ul style="list-style-type: none"> Operating theatre Intensive care room Premature baby room
			

Allocation of group numbers and classification of safety services



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Classification	... with medical staff	... and type of contact
Classification of a medical location shall be made in agreement with <ul style="list-style-type: none">the medical staffthe health organization concerned orthe body responsible for the safety of workers in accordance with national regulations.	It is necessary that the medical staff indicate which medical procedures will take place within the location. Based on the intended use, the appropriate classification for the location shall be determined	Classification of a medical location should be related to the type of contact between applied parts and the patient, as well as the purpose for which the location is used.

is demanding a risk analysis in consideration of e.g.

- Use of applied parts
- Dangerous electrical currents via body
- Insufficient quality of power supply / interruption

Group definitions according IEC 60364-7-710



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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.					

In group 2 medical locations, the medical IT system is mandatory 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 (see page before)

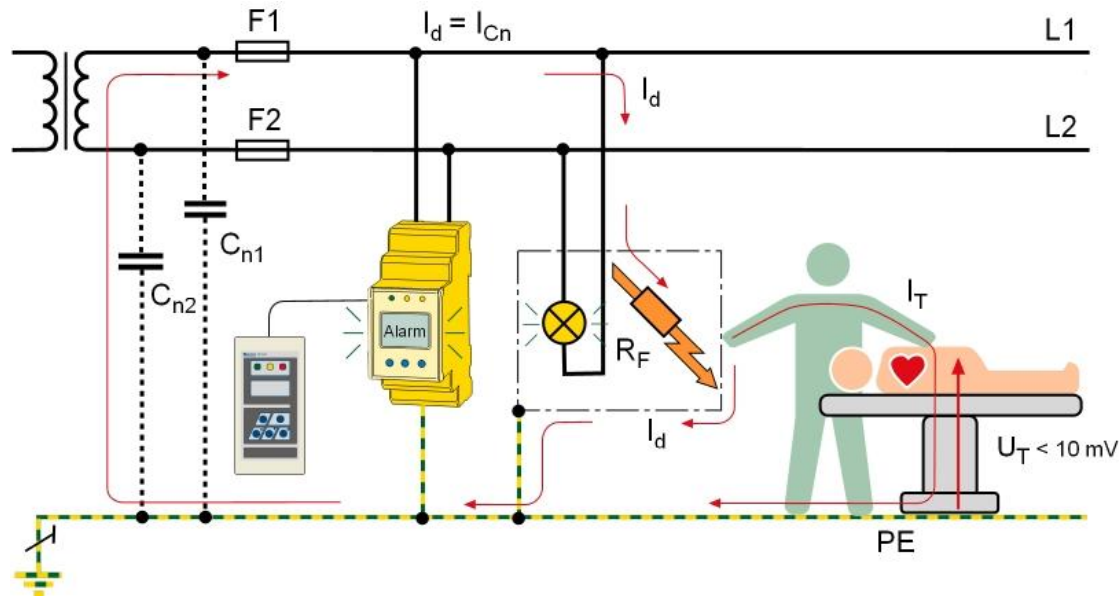
The use of an IT system is the backbone of a reliable power supply

- When a first insulation fault occurs the power supply is not interrupted by tripping of a protective device
- Medical electrical equipment continues to function
- Fault currents and touch voltages reduced to uncritical level
- No panic breaks out in the operating theatre because power failure is averted

Group 2 locations – advantages by the use of an IT-System



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1st advantage – in the event of a first fault R_F

- only a very low current I_d flows
- Fuse does not trip
- Alarm indicated by an ISOMETER® (IMD)
- **No danger for patients, the power supply is guaranteed**
- **Maintenance on scheduled date**

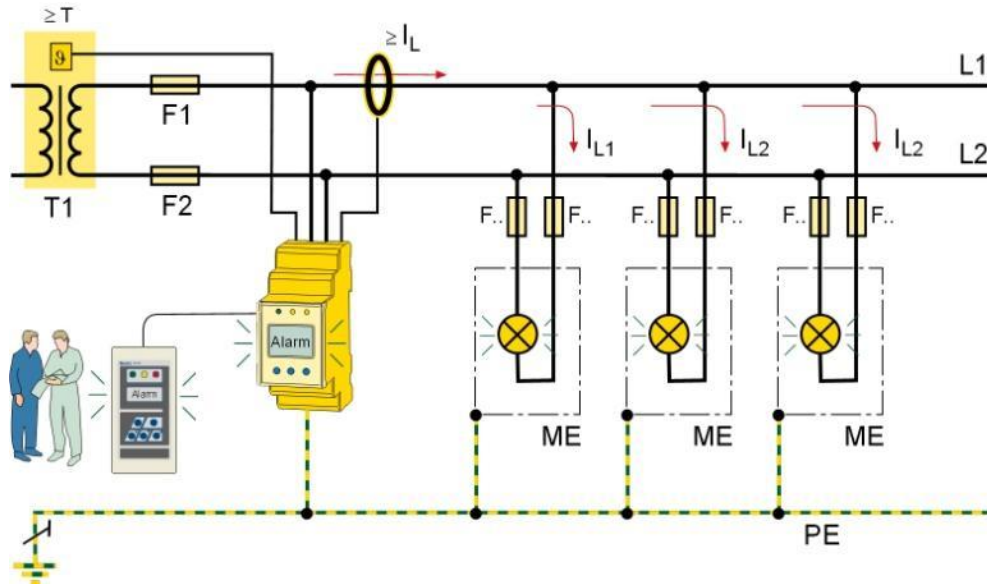
2nd advantage - in the event of a first fault R_F

- Minimized touch current I_T respectively upcoming touch voltage $U_T \leq 10 \text{ mV}$
- **No danger of life for patients e.g. at open heart surgeries or inter-cardiac processes**
- **No danger for medical staff**

Load - and temperature monitoring in IT-Systems



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Note:

In the main feeder of the IT system transformer overcurrent protective devices are only used for protection against short-circuits, so that an overload does not lead to a power failure !

1st advantage – monitoring load current I_L

- Measurement of load current by ct
- Exceeding of tolerable transformer power (load current) will be indicated immediately when using additional medical equipment

2nd advantage – monitoring temperature

- Measurement by PTC resistor in transformer winding
- Even low rising of the temperature of the transformer winding will be indicated
- Fire risks and damages to property by overheating will be avoided

Monitoring the medical IT system transformer

- Monitoring of overload and high temperature for the medical IT transformer is required ...
- but no circuit breaker 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.



The insulation monitoring device (IMD) (710.413.1.5)



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Requirements for insulation monitoring device (IMD)

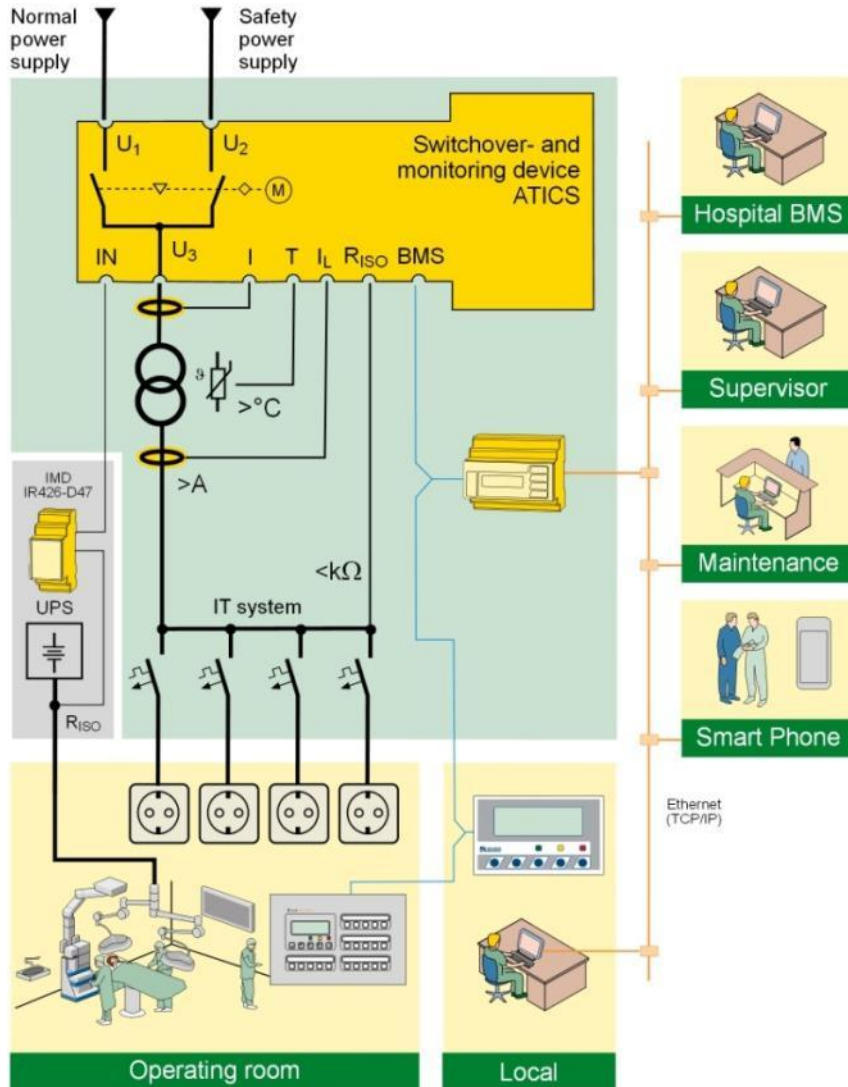
- For each group of rooms serving the same function, at least one separate medical IT system is necessary.
- The medical IT system shall be equipped with an insulation monitoring device in accordance with IEC 61557-8 with the following specific requirements:
 - a.c. internal impedance $> 100 \text{ k}\Omega$
 - the test voltage $\leq 25 \text{ V d.c.}$
 - injected current $\leq 1 \text{ mA peak}$, even under fault conditions
 - indication when insulation resistance $\leq 50 \text{ k}\Omega$
 - a test device shall be provided



How to inform the staff



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- **The supervision staff**
 - Views the state of each medical location
 - generates event reports
 - Set alarm thresholds e.g. temperature
- **The maintenance staff**
 - is informed by SMS
 - Consults via PC the electrical state of the operating room
 - Can indicate its handling of the fault
- **The nurse**
 - Test the insulation monitoring device at start-up of operating room
 - Is warned of an electrical or insulation fault
 - Uses the control panel to monitor environmental
 - Is notified of any work performed by maintenance personnel
- **The surgeon**
 - Remains concentrated on his work
 - Benefits from stability and security of the electric power supply

Requirements for Remote alarm indications

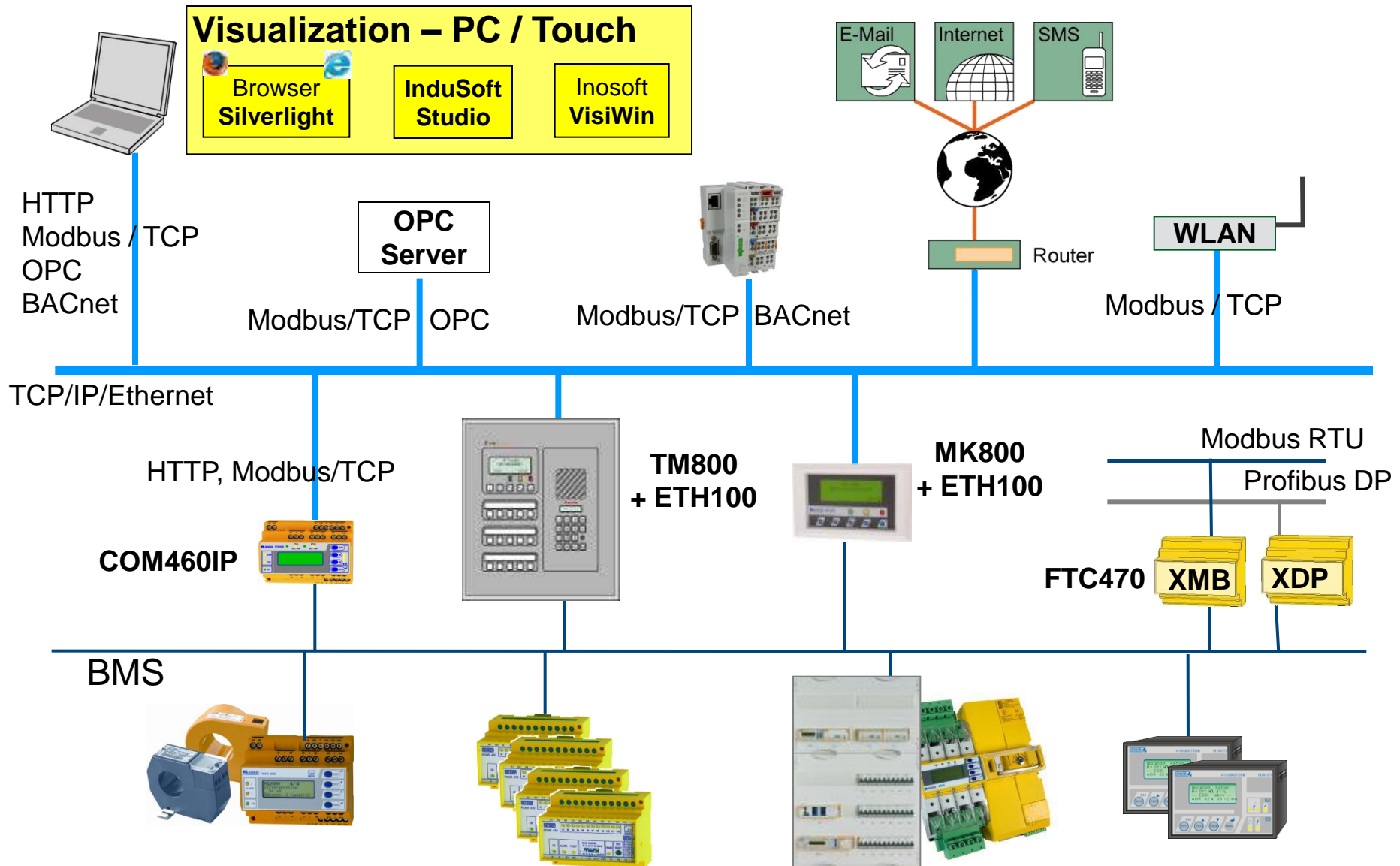
- For each medical IT system, an **acoustic and visual alarm system** shall be arranged at a **suitable place** so that it can be permanently monitored by the medical staff:
 - A green signal lamp to indicate normal operation
 - A yellow signal lamp which lights when the minimum value set for the insulation resistance is reached. It shall not be possible for this light to be cancelled or disconnected
 - An audible alarm which sounds when the minimum value set for the insulation resistance is reached. This audible alarm may be silenced.
 - The yellow signal shall go out on removal of the fault and when the normal condition is restored
 - Note: Additionally overload and overtemperature of the IT system transformer must be indicated.

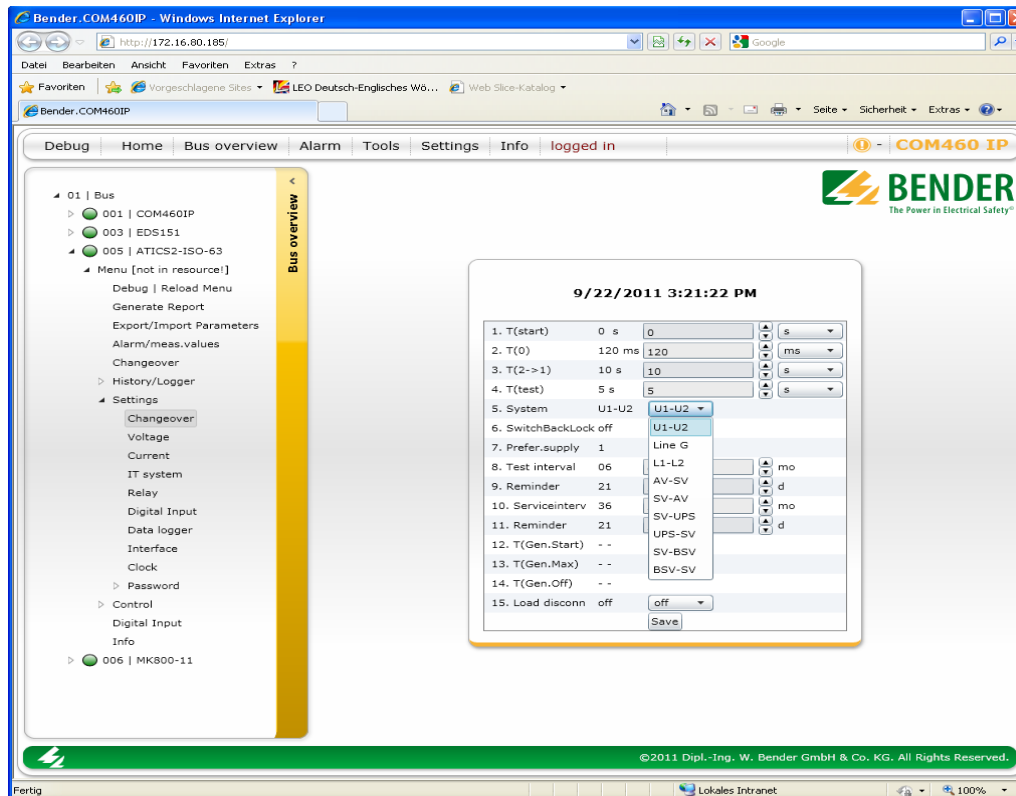


Communication possibilities



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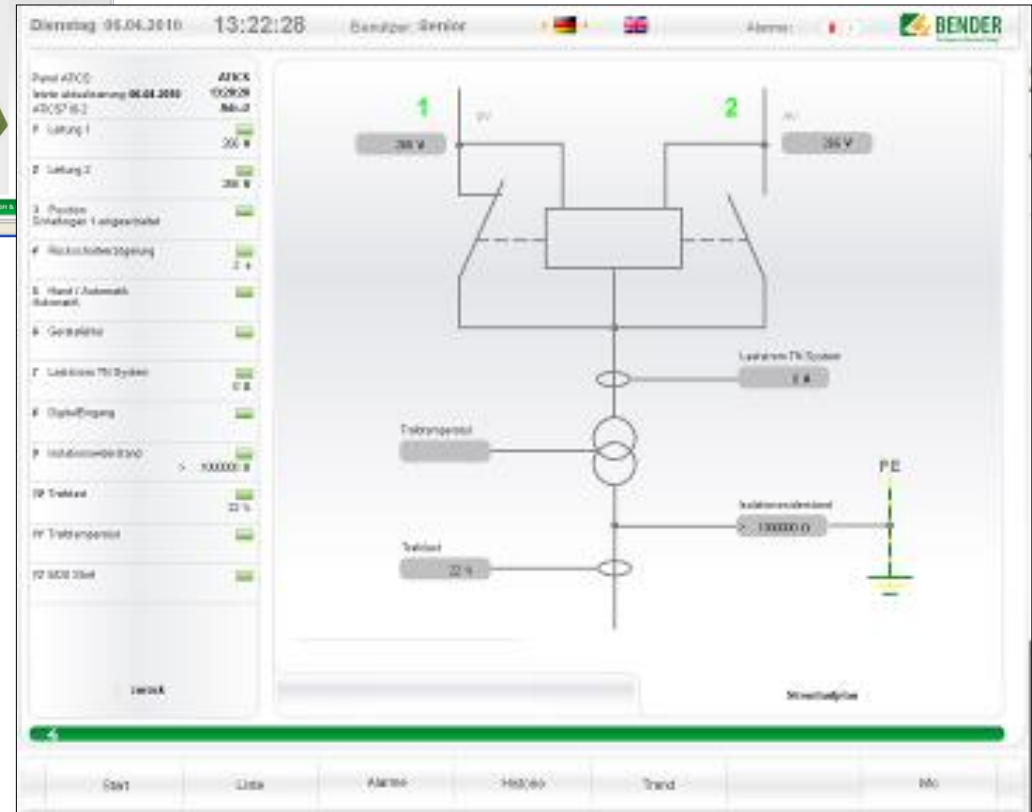
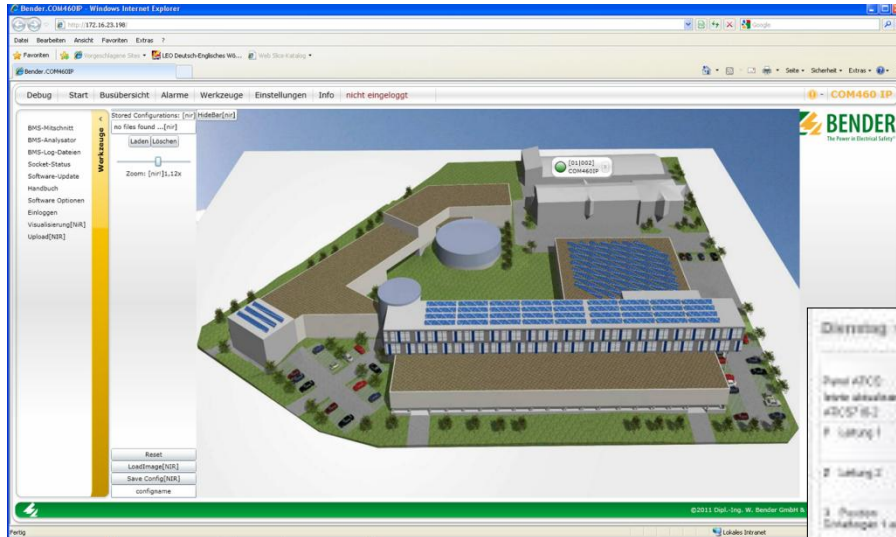


- Parameter setting online and offline
- PDF reports
- E-Mails / SMS
- Documentation of alarms, time stamp (history log)
- Complete data logging
- Customer specific text fields

Gateways to Ethernet – Modbus/TCP



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Requirements from IEC 60364-7-710

710.313 Power supply

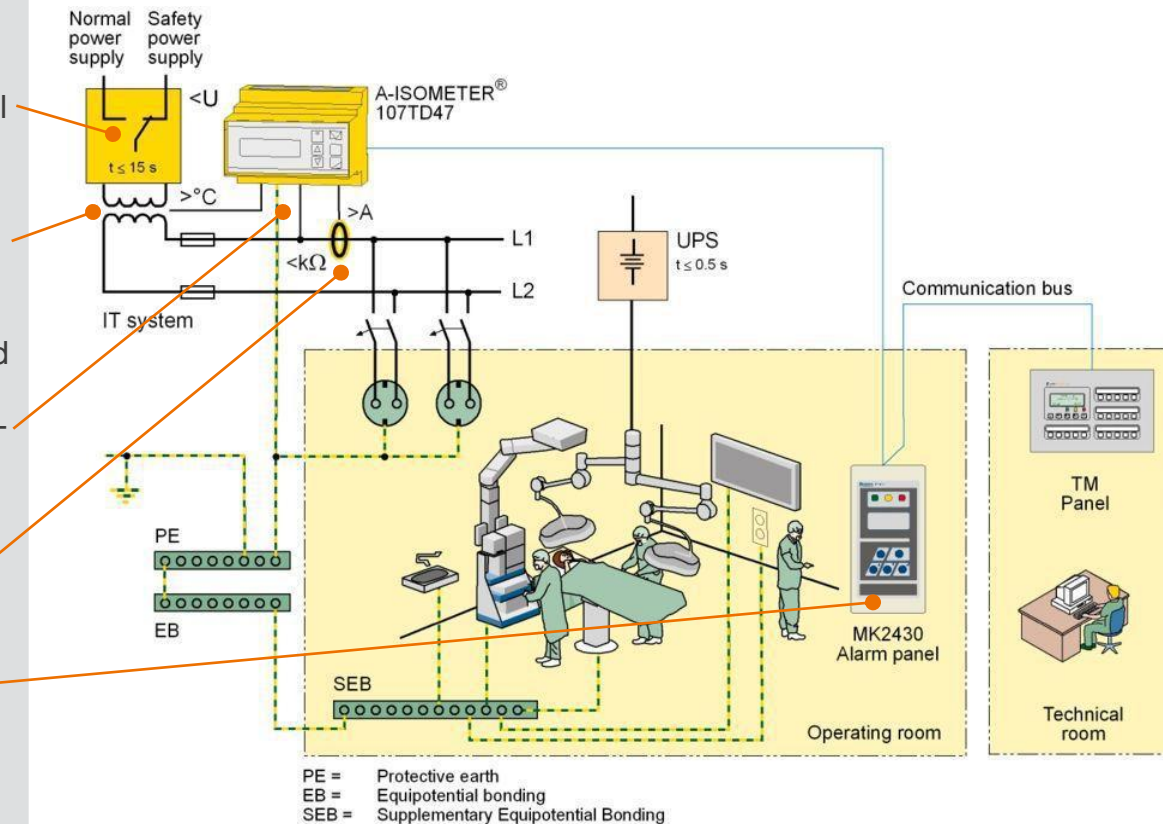
- Automatic change-over main distribution network and electrical safety source

710.413.1.5 Protection

- Group 2 medical locations IT system for Medical electrical equipment and systems for life support, surgical applications and other equipment
- Insulations monitoring for each IT system
- Indication at $< 50 \text{ k}\Omega$
- Monitoring of overload and high temperature for medical IT system transformer
- Acoustic/visual alarm system

710.512.1.1 Equipment

- Transformers secondary side max. 250 V AC, 1...10 kVA



Where is the insulation fault?



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IEC 60364-7-710: 413.1.5.4

It is recommended that the first fault be eliminated with the shortest practicable time



But how ?



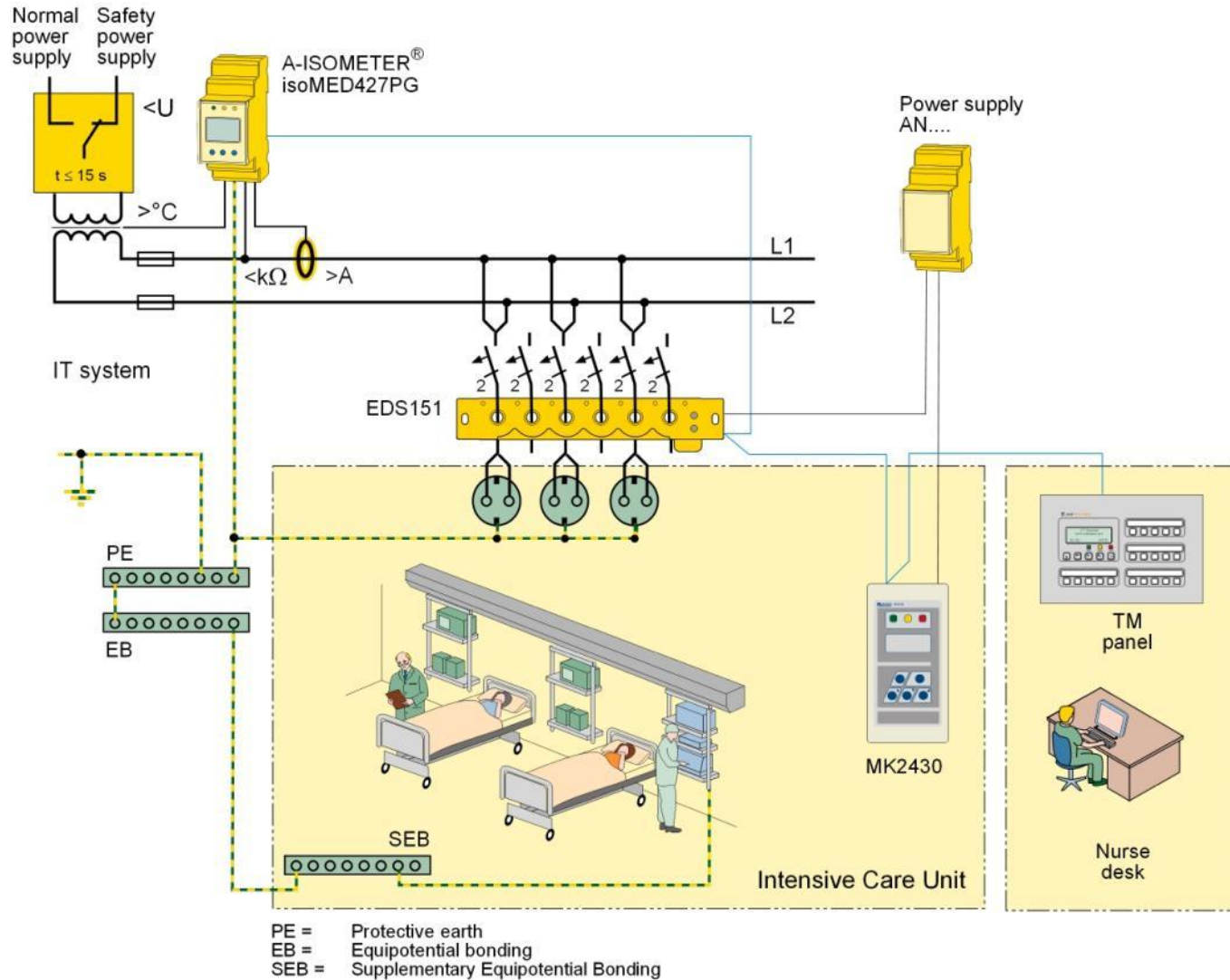
The solution

Earth fault detection system

Design of an insulation fault location system



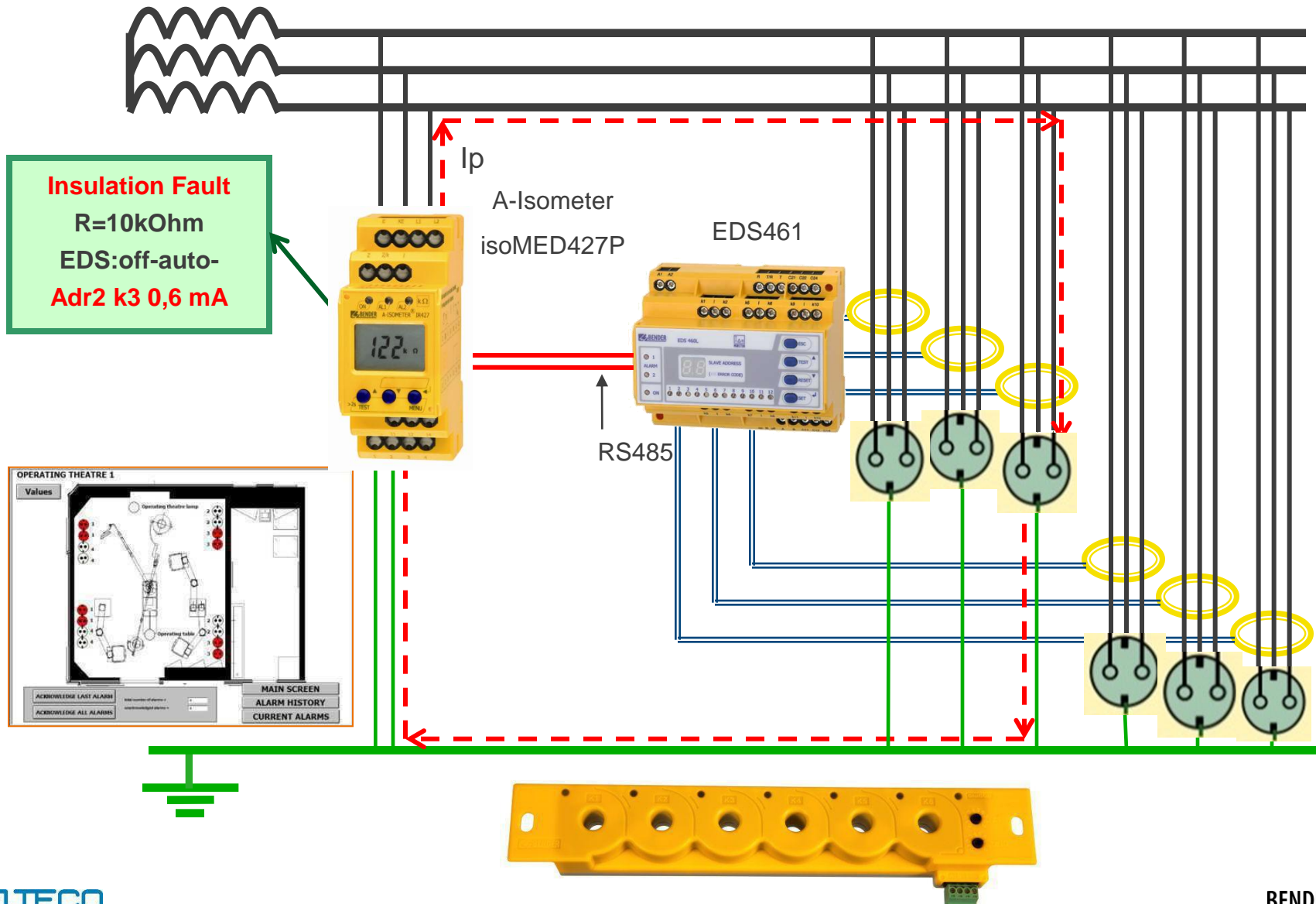
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Fault location in practice



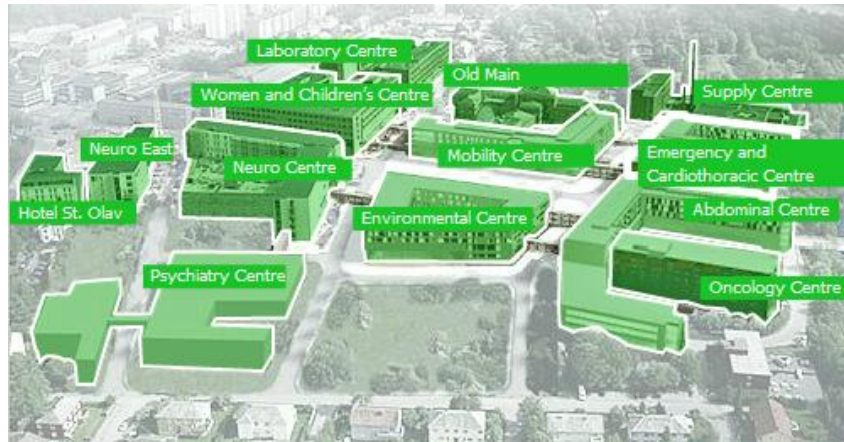
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ELECTRICAL SAFETY

solutions also for hospitals in
Norway – e.g.

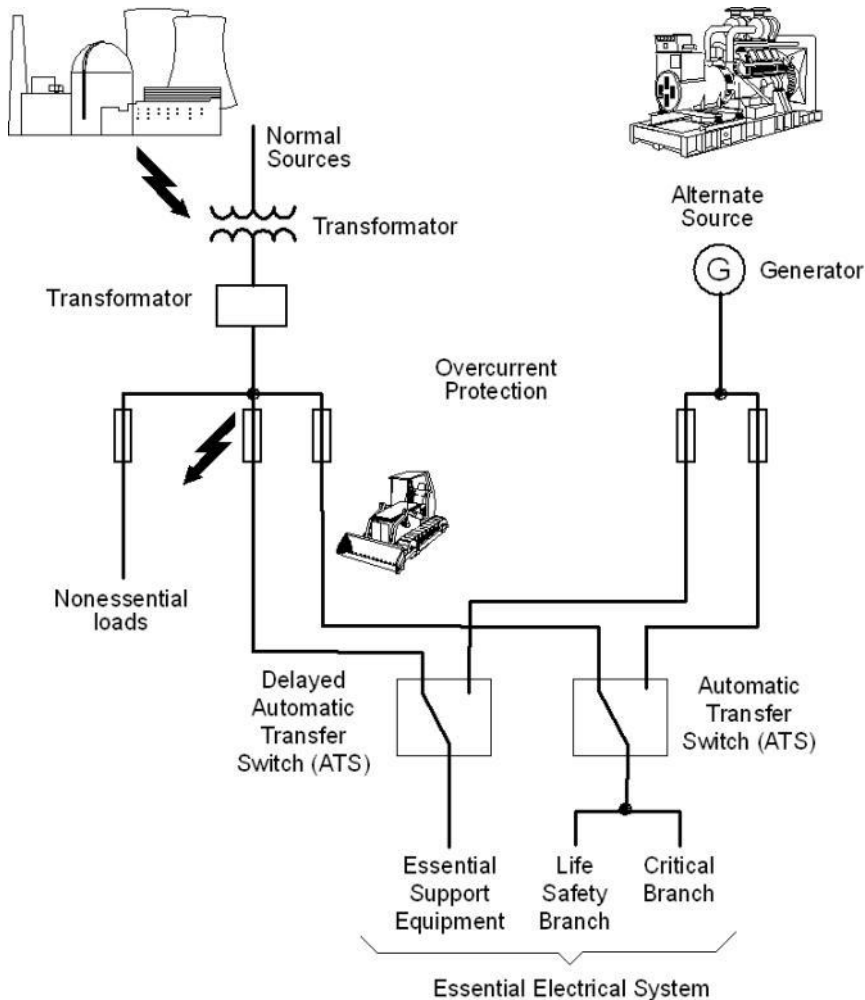
St. Olav - Trondheim



Why automatic transfer switches ?



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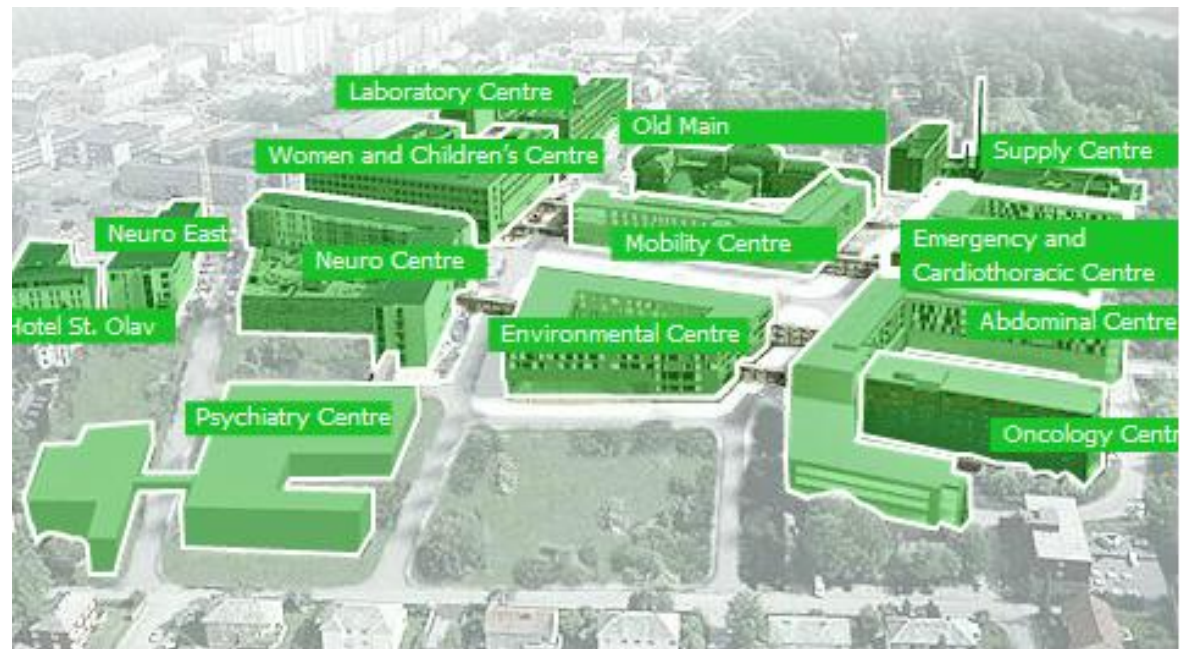


- Failure of public power supply by lighting, storm,
- False switching operation
- Mechanical reasons
 - damage, e.g. digger damages cable btw. two buildings
 - Loose , faulty terminal connections



Power supply solutions used in

- Mobility Centre
- Emergency and Cardiothoracic Centre



Power supply in St. Olav



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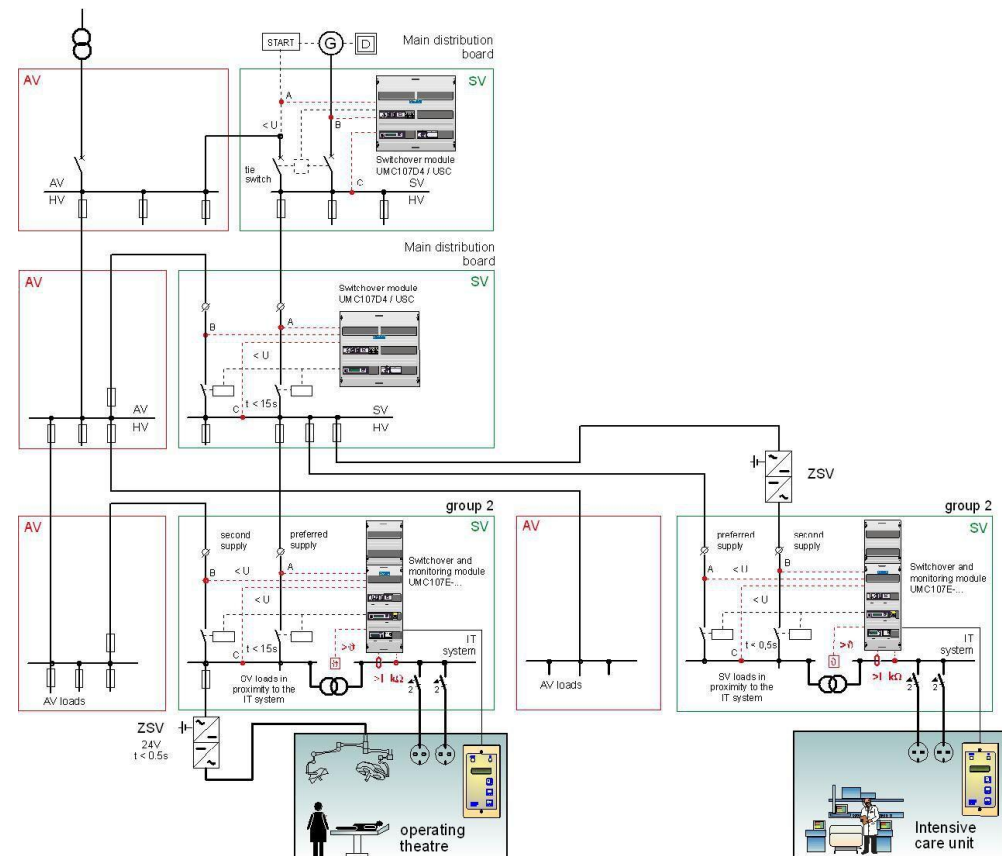
SIKRINGSSTØRRELSE KAPAKTETSETTE	TYPEN	FEMKELEMMER	KABEL/KLIPS NR.	TVÆRSNITT OG TYPE (mm²)	KABELLENDE (m)	KW	BELASTINGS- OBJEKT
							DATA SPENNING: 230V FREKVENS: 50Hz FORD.SYSTEM IT Ik3-MAX: 5,5kA Ik2-MIN: 2,5kA KAPSLING IP2XC DPPDELING/FORM: NEK EN 60 439-3
	63A	611SB11S-13		2x16 BFSI CU XXX			STIGER FRA 611SB11SP NBDSTRØM
	63A	612SB11S-13		2x16 BFSI CU XXX			STIGER FRA 612SB11S UPS
MEDIS NETTOVERVÅKER UMC 107 E		BENDER-BUS		2x0,5 YFSK			BENDERBUS FRA FORL. XXXXXXXXX JORDES KUN I EN ENDE
ES 0107/8000		BENDER-BUS		2x0,5 YFSK			BENDERBUS TIL FORL. XXXXXXXXX JORDES KUN I EN ENDE
8 kVA				2x0,5 YFSK			24V TIL TABLÅ JORDES KUN I EN ENDE
VERDER ETTER TRAFD:							
I _{kmax} =0,39kA							
I _{kmin} =0,27kA							
SEKSJON 1							
ROM SB11.166							
10A B		.10	2x15 PN/PR	*	*		LYS I TAK PLEESONE SB11.166
10A B		.11	2x15 PN/PR	*	*		LYS I TAK PLEESONE, FAMLSONE, BAD SB11.166, 11.167, 11.168
16A B		.12	2x2,5 PN/PR	*	*		LYS OG STIKK OVER BENK OG KJØLESKAP SB11.166
16A B		.15	2x2,5 PN/PR				STIKK ARB.PLASS OG MED.SØYLE SB11.166
16A B		.16	2x2,5 PN/PR				MED.SØYLE SB11.166
16A B		.17	2x2,5 PN/PR				MED.SØYLE SB11.166
16A B		.18	2x2,5 PN/PR				STIKK I KANAL Ø/SENG, TV OG BAD SB11.167, 11.168
16A B		.19	*	*	*	*	RES
16A B		.20	*	*	*	*	RES



Total project quantity:

More than 100 pieces

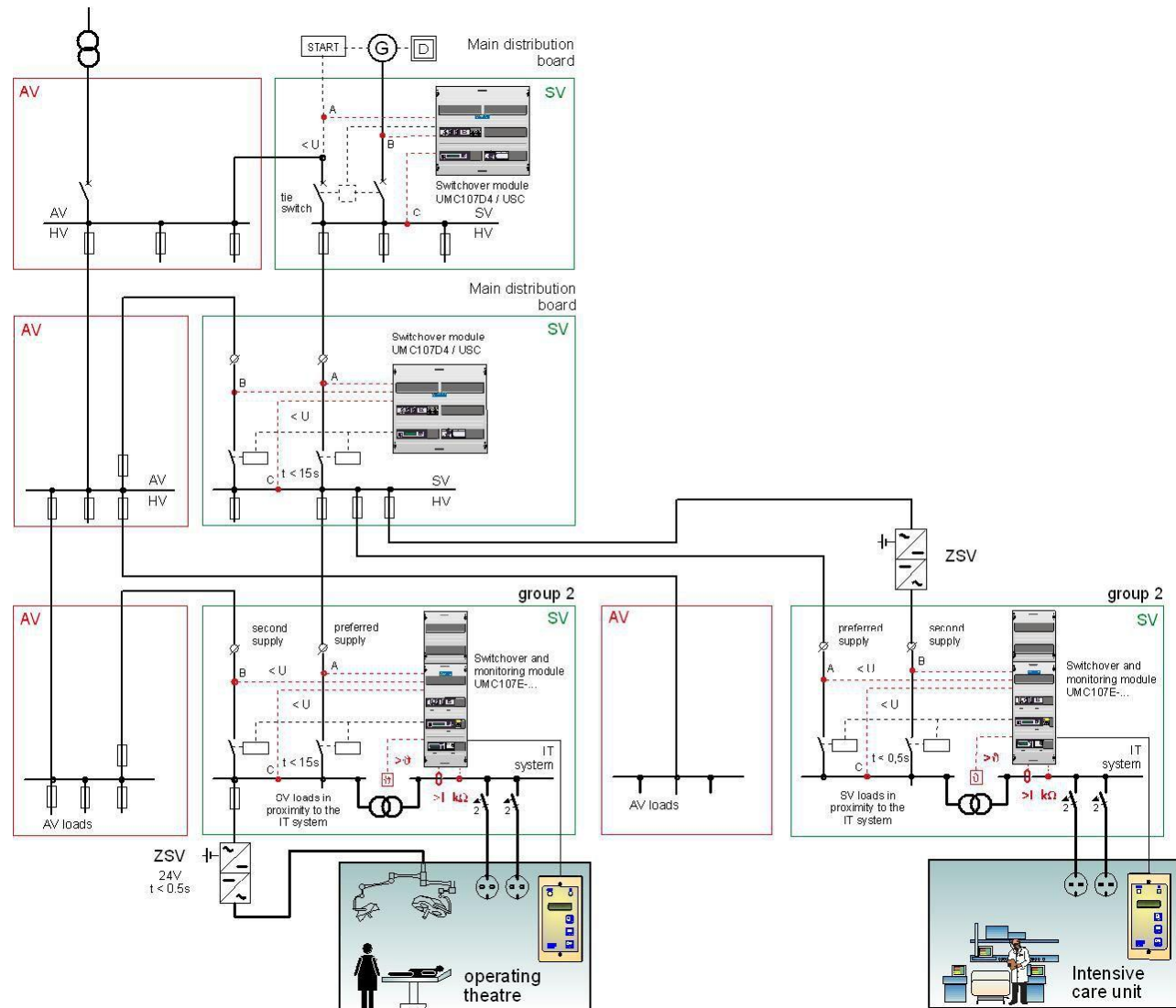
switch over unit UMC107E-65-400(400V) together with indication panel MK2418-12 and SMO482P-12



Power supply in a "big" hospital

Operating theatre and Intensive: $SV/ZSV \leq 0.5s$

AV = Normal power supply source
 SV = Safety power supply source
 ZSV = Special safety power supply source
 HV = Main distribution board

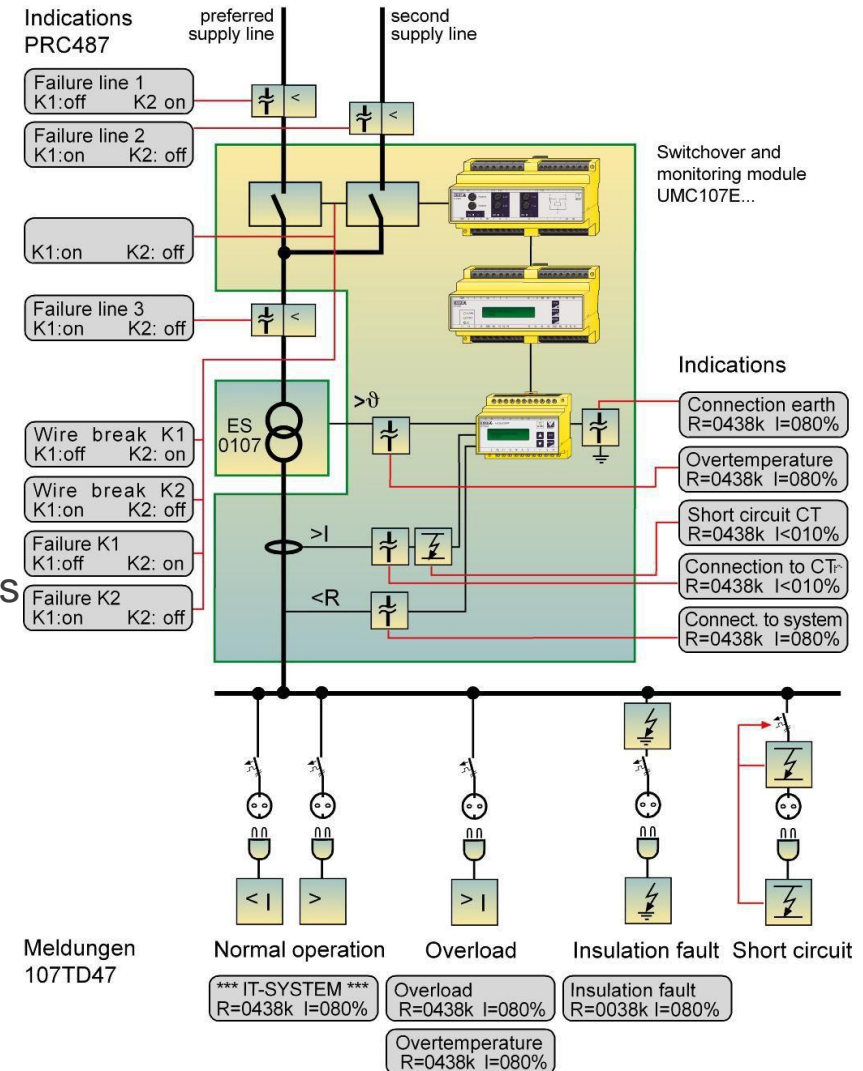


"First fault" in the switchover module



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- Section 710.521.6 "a single fault in the control system must not lead to a failure of the two supply lines".
- Which lead to **changeover and indication**
 - Voltage drop
 - Faults at the switching elements (open circuit, failure main contact)
 - Contact fault load switch (welding)
 - Unintentional switching of switching elements
- Which lead to **indication** and therefore to immediate service requirement
 - Failure control voltage
 - Open circuit coils
 - Processor control fault control device
 - Period of on/off switching of the main switching elements elapsed



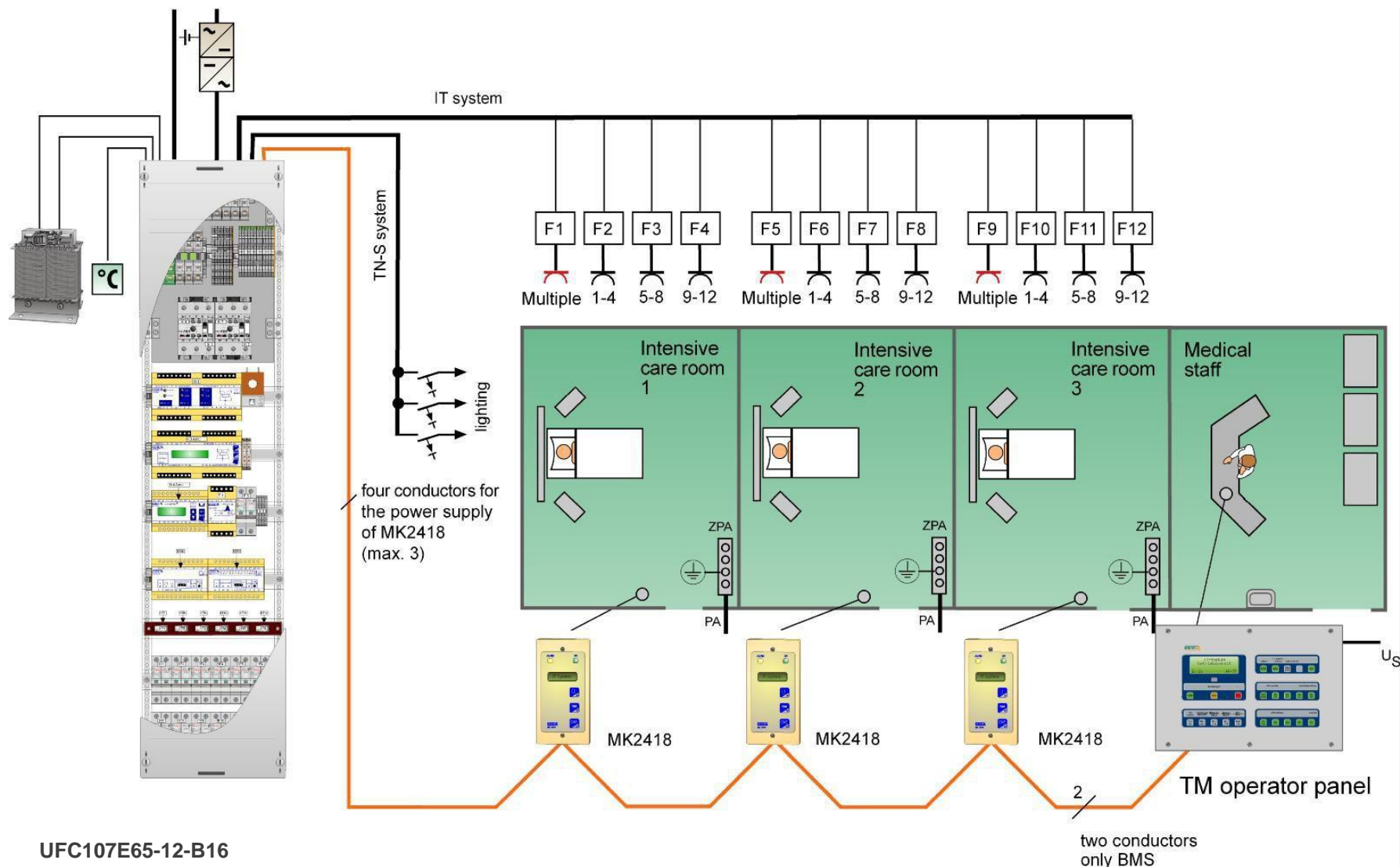
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Installation example for an intensive care unit IT system for 4 beds (or incubators)



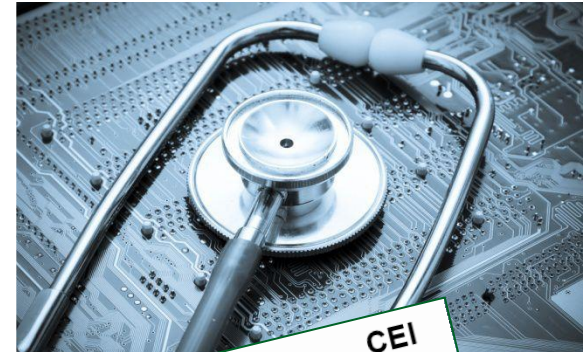
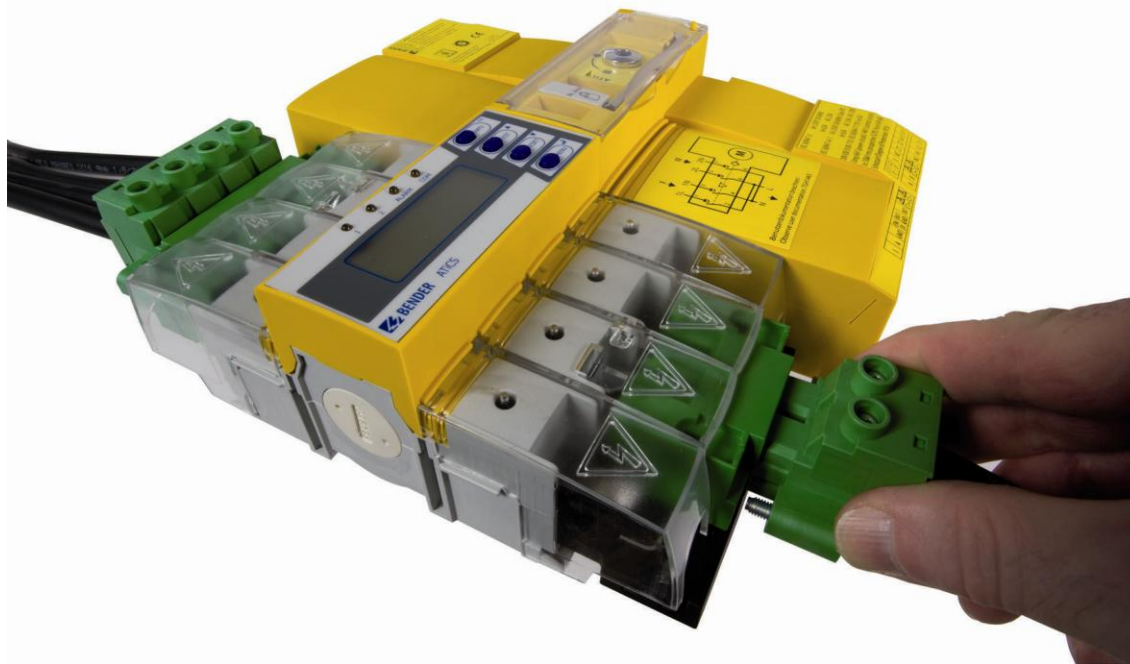
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UFC107E65-12-B16

- Universitetssykehuset Ullevål (Oslo)
 - Ahus (Oslo)
 - Radiumhospitalet (Oslo)
 - Martina Hansens Hospital (Oslo)
 - Sykehuset Buskerud HF (Drammen)
 - Sykehuset Vestfold HF (Tønsberg)
 - Sykehuset Telemark HF (Skien)
 - Stavanger Universitetssykehus HF (Stavanger)
 - Nordlandssykehuset (Bodø)
 - Sykehuset Innlandet HF (Lillehammer)
 - Sykehuset Innlandet (Gjøvik)
 - Sykehuset Innlandet (Hamar)
 - Helse Sunnmøre (Ålesund)
 - Sørlandets Sykehus HF (Kristiansand)
 - Sørlandets Sykehus Flekkefjord
 - Sykehuset Østfold (Moss)
 - Sykehuset Elverum, Førde Sentralsykehus (Førde)
 - Helse Fonna HF (Haugesund)
- and more

ATICS...



Definition

- Functional safety is the part of the overall safety of a system ...
...operating correctly in response to its inputs, including the safe management of likely operator errors, hardware failures and environmental changes.

Objective of Functional Safety

- ... is freedom from unacceptable risk of physical injury or of damage to the health of people either directly or indirectly.

Achieving Functional Safety

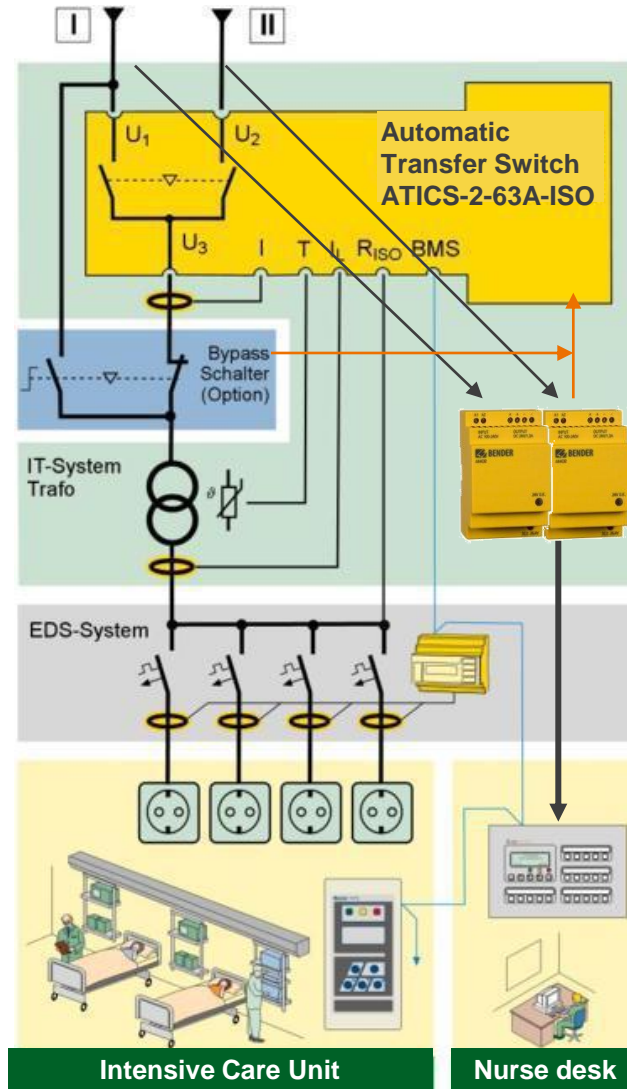
This involves several concepts, including:

- 1. Identifying what the required safety functions are.
- 2. Assessment of the risk-reduction required by the safety function.
→ Safety Integrity Level (SIL) Assessment. → **SIL 2**
- 3. Ensuring the safety function performs to the design intent.
→ IEC EN 61508.
- **Neither safety nor Functional Safety can be determined without considering every specified safety function and the system as a whole and the environment with which it interacts.**

Certifying Functional Safety

- Any claim of Functional Safety for a component, subsystem or system should be independently certified to one of the recognized Functional Safety standards → IEC EN 61508
- Early cooperation with the certification institute → TÜV Munich
- Products and Processes that manage the whole lifecycle of the product, including:
 - Development
 - Production process
 - Planning
 - Commissioning
 - Maintenance
 - Lifecycle managed by qualified and competent engineers





- Transfer time
 - $t \leq 0,5 \text{ s} \dots 100 \text{ s}$
 - Free choice of preferred Line
- For Intensive Care Units (ICUs)
 - Automatic fault location system with EDS-System
 - Uninterrupted operation during test or service using a bypass



Summarize.... electrical safety



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What's the target ?

How to do ...

Where to find ...

<ul style="list-style-type: none"> No Danger for the patient through shutdown of the power supply and with that defects of equipment and systems 	<ul style="list-style-type: none"> Redundant power supply with automated change-over between two power sources Main Supply / Safety Supply / UPS 	<ul style="list-style-type: none"> 710.512.1.6 710.537.xxx 710.562.7 710.564.xxx
<ul style="list-style-type: none"> No Danger for the patient through insulation-faults and with that defects of equipment and systems 	<ul style="list-style-type: none"> IT-System Insulation-monitoring Transformer with load- and temperature-monitoring 	<ul style="list-style-type: none"> 710.512.1.6 710.531.3.1
<ul style="list-style-type: none"> No tripping of safety-equipment through Overload and Avoiding Fire through Over-Temperature 		<ul style="list-style-type: none"> 710.531.3.1
<ul style="list-style-type: none"> No Danger for the patient through high leakage-currents 	<ul style="list-style-type: none"> Requirements for the Transformer which supplies the ungrounded system 	<ul style="list-style-type: none"> 710....
<ul style="list-style-type: none"> Early information before a material damage or endangerment of people occurs – planned maintenance 	<ul style="list-style-type: none"> Information for the user at a central location 	<ul style="list-style-type: none"> 710.531.3.1 710.537.6
<ul style="list-style-type: none"> Ensure the functionality 	<ul style="list-style-type: none"> Periodic verification 	<ul style="list-style-type: none"> 710.6.2

Summarize.... electrical safety



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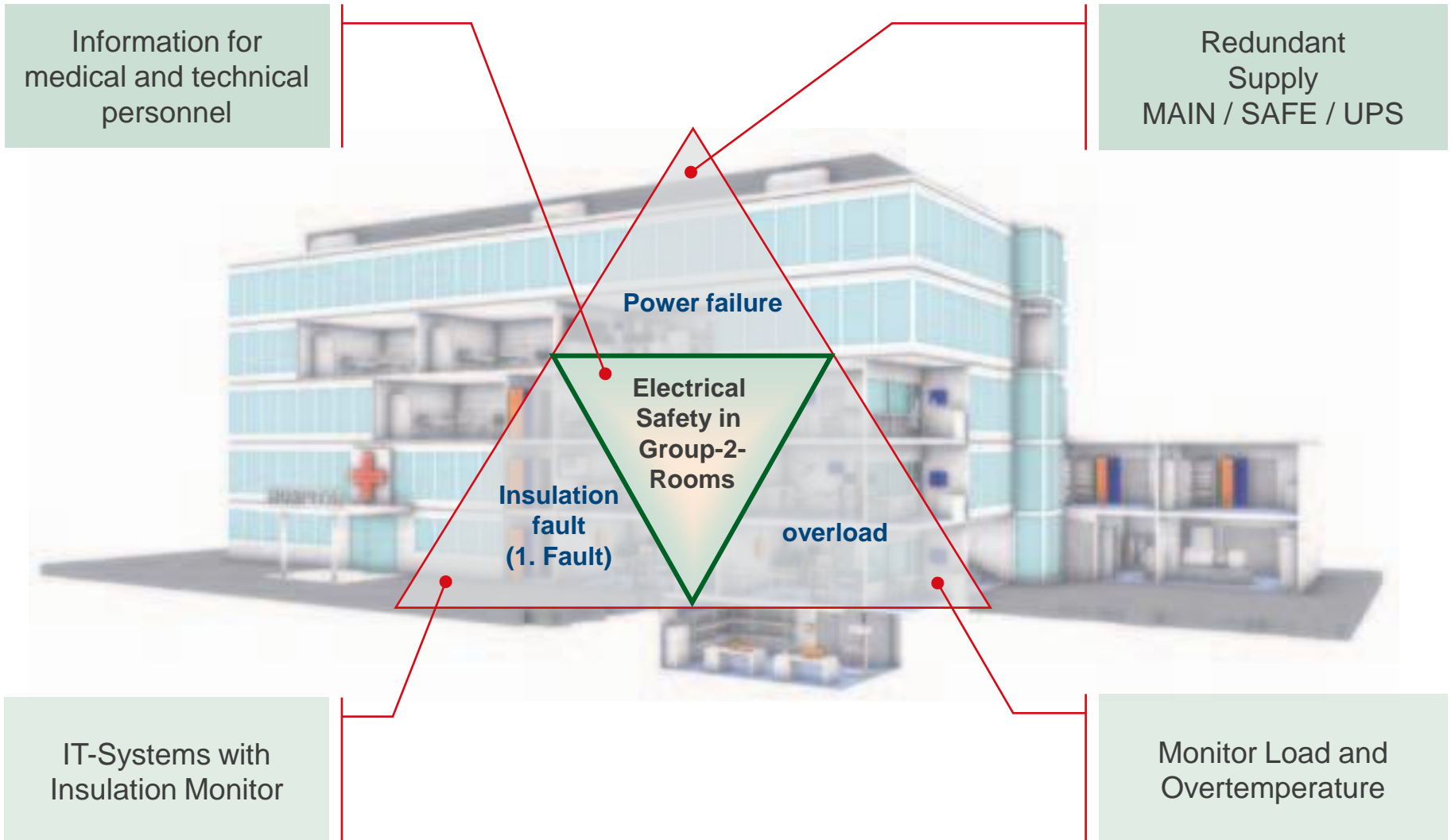
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Electrical Safety in Group-2-Rooms



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Thank you for your attention!



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