Medical Locations

Medical Surgical Robot Equipment

A New Circuit Concept to Succeed Medical IT circuits

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Background – Ian Chell

- 22 years with Siemens Medical as a power/control apprentice and X-ray Engineer. Many Germany-based product courses. MSc Medical Electronics and Physics.
- Moved to MHRA for 6 years (1998 – 2004) as a Medical Device Specialist, led and produced the first version of MEIGaN.
- Policy leader for radiations in Dept of Health. Invited onto the WP for the 2017 version of HTM 06-01.
- Now runs training venture - Medical Locations.
- Consultant on medical device electrical safety.
- Support the Police - two cases this year – one had a death inquest two weeks ago and there will be implications for medical locations.
- I will circulate the Reg 28 notice to CIBSE.

Medical Locations

- Offers governance and technical training on medical locations and can also offer shadowing of such a process.

- www.medical-locations.co.uk

- Protective/Supplementary diagrams on final testing page.

Medical Locations - Designing

- It is important to follow a strict governance policy to group and design a medical location. This means clinical staff completing templates to state what devices are being used, where in the room, how many and the clinical application. This should be on day one of the project.
- From this the designers can group the location, put the supplies in the right place and establish if a UPS is required and for how long.
- Quite often, even after training, a lack of interest by leaders with this governance approach means it was futile – recent training feedback ”they’ve probably gone back to their silos”.
- It is crucial to ensure the installation meets the latest BS7671 A2 and A3 amendments especially for the new measurement and wiring schedule requirements. Any rooms having radiology equipment replaced need to have the room compliance checked especially the earthing and supplementary equipotential bonding.
- New foreseeable risk – EPO / contactor switchgear with new radiology interventional equipment - and fit lamps to all on/off pushbuttons. Ensure remote on/off is fitted when the contactor is in another room. Change the socket-outlets in group 2 – contact wear.
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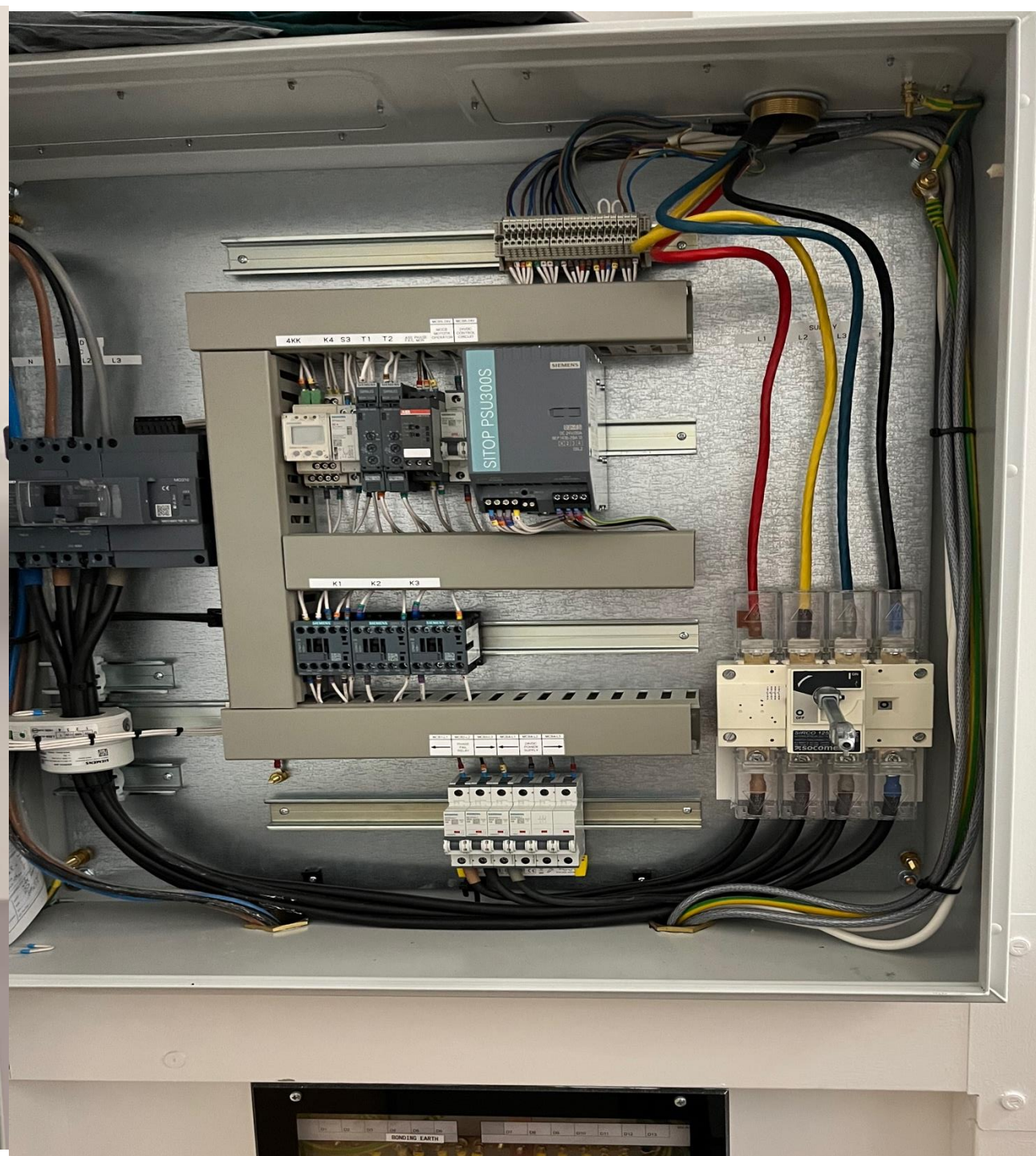
UK Issues

- Silo working. Estates have the responsibility for wiring but not what devices are used in the location.
- Clinical staff need to respond to a day one questionnaire - how many devices, where they are used and how.
- Installing a scanner? Somebody should add up how many devices will be used in that scanner room at one time. PET CT example….
- Electricians need to be trained and accredited – hospital wiring requires specialist knowledge, yet there are no regulatory controls like with homes. The extra training required is around 5 hours.
- Not reading A2 requirements.
  - There will probably be a new template for BS7671 A4 and the SEB readings will probably be undertaken before connection. Several A2 requirements are still being missed by electricians!


MAIN SWITCH
SUPPLIED FROM
SB2AB-1-3
RHC SPECT-CT
160 AMP


SITOP PSU300S
4KK K4 S3 T1 T2
K1 K2 K3
BONDING EARTH

Background – Medical TNS

- Medical TNS is a new concept that can replace Medical IT.
- I was recently asked to draft guidance on Medical Surgical Robot Equipment (MSRE).
- The solutions for this were interesting but it highlighted 3 main points that require the hospital electrical safety group to review.
  1. Establish the total load of the whole MSRE and the load of ME equipment that will be used at the same time. Intuitive is around 3.5 kVA plus any electrosurgery options etc – this is 35-50% of IPS load capacity
  2. Establish if any module requires a time-delay MCB or RCBO (difficult to spot in the Intuitive manual as it is only highlighted by an asterisk and footnote).
  3. Calculate the UPS on time for the new increased load as this may need a new UPS.

Patient Leakage Current

- The current flowing between the applied part of the medical device and the patient . Concern is the AC component up to 200 Hz measured in microamps. Measured by clinical engineering using a low pass filter to remove frequencies above 750Hz.
- The risk is only a real risk when the skin (1k ohm) is broken (no 1k resistor in the patient leakage circuit).
- IEC 60601 build guidance has standards and the key focus for limiting this current. **No longer any need for isolated mains supply circuits**.
- ***If the manufacturer of the device deems an isolated supply is required, they fit one to the device.***
- BS7671 supports this risk with supplementary equipotential bonding in group 2 medical locations. I call it the clean earth, which minimizes EMI and patient leakage currents. It is crucial to not connect the clean earth to extraneous except with one connection at the EBB.

1980’s IPS introduced

(Could be the 70’s)

- No medical device regulations.
- Early version of 60601
- You could research and build new medical devices without any formal controls.
- No accredited approved test facilities to independently test devices.
- Material technology meant that device applied parts were conductive metals. For example, power injector plungers were made of metal.
- No RCBO’s.
- BS7671 not aligned with 60601

2005

- Medical Device earth leakage value increased X10 to 5mA and 10mA with SFC. IPS remains at the old value of 0.5 mA

2025

- Comprehensive medical device regulatory framework.
- IEC 60601 series is comprehensive and has essential requirements for the general design.
- BS7671 now references 60601.
- Accredited test facilities must independently certify devices before marketing and MHRA requires a balanced compliance approach for new research devices.
- Modern materials mean applied parts are no longer conductive for example a power injector plunger.
- RCBOs can protect individual power circuits.
- Significantly more Class II devices.
- Supplementary Equipotential Bonding – clean earth radial system to support the requirement of IEC 60601 single fault condition, to reduce EMI risks and contribute to minimising patient leakage currents (by ensuring no potentials on the protective earth).

Earth Leakage Faults - Evidence of Device Failures in 2025

- NPAG Findings "Generally, everyone agrees earth leakage faults are rare & visual inspections find many more issues than electrical safety testing."
- My own limited survey revealed:
  - Some sites had no earth leakage failures
  - Some did not record this – only patient leakage! Staff could not recall any earth leakage failures.
- Initial evidential conclusion that in 2025, this issue appears to be significantly better than in the last century. Maybe even better than 10 years ago? I am already convinced earth leakage failures are now only a minor risk.

Medical Locations – 4 Fundamental Risks

1. EMI and patient leakage currents – resolved with SEB clean earth (radial) system in group 2.
2. Risk of Mains Failure – resolved with UPS
3. Risk of Discontinuity – resolved with Medical IPS/IT
4. Support the IEC 60601 single fault condition – combination of the above – not for now.

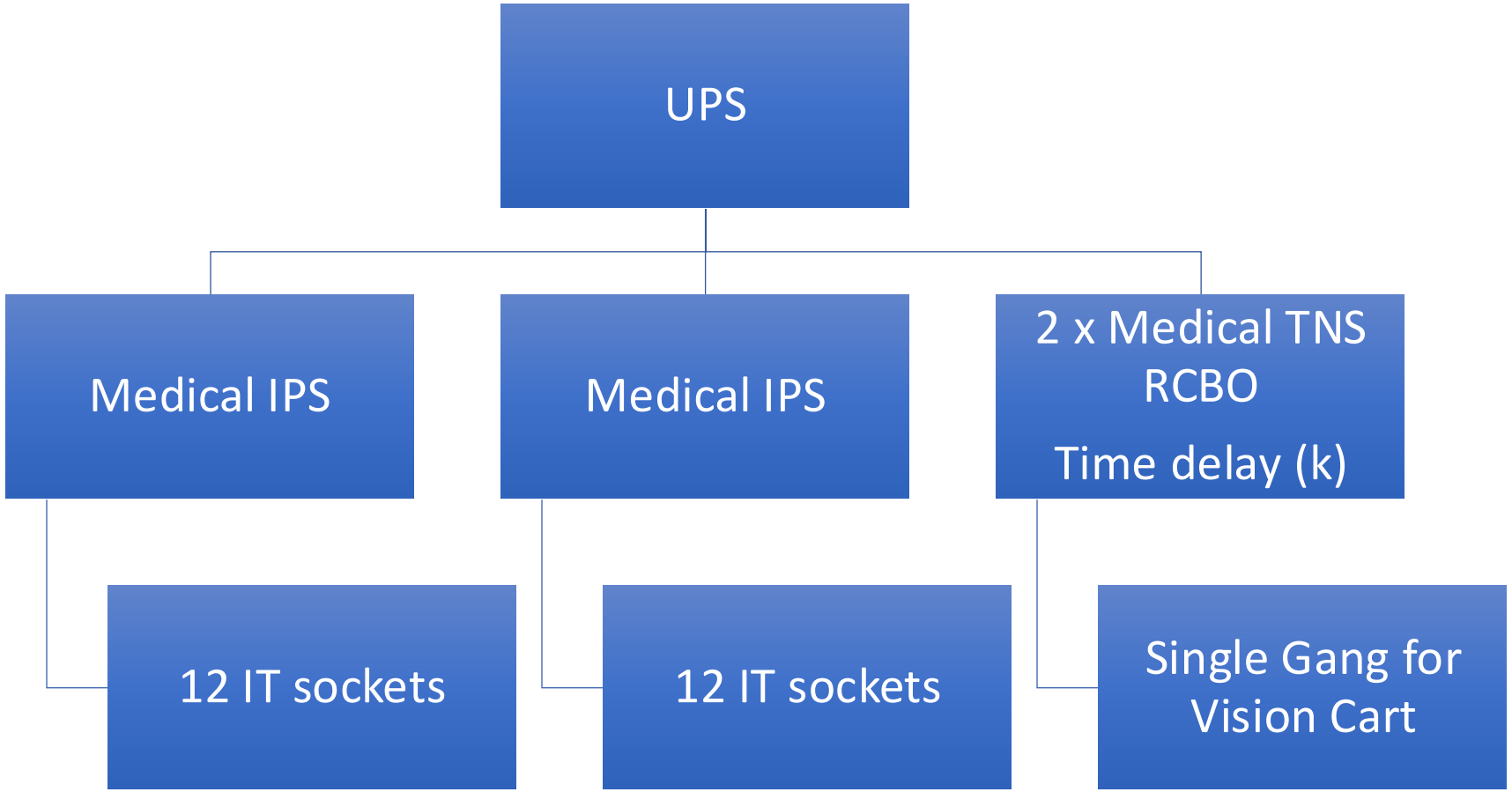
Medical IT Circuits - Purpose

- Medical IT with an IPS supply is to prevent one faulty medical device taking out the whole circuit. Minimise the risk of final circuit discontinuity.

- IET GN7 guidance states *"The isolating transformer (BS7671 710.512.1.1) prevents the loss of a supply of* ***all*** *connected* ***(medical)*** *equipment when a first fault to earth occurs on a single item."*
- It also states that it is to limit leakage currents – this is what I am challenging based on my previous arguments on how device safety and design is now resolved with IEC 60601 plus in 2005, the device earth leakage values were increased to 5mA in normal condition and 10mA under single fault condition. IET GN7 states it is 0.5mA – this was to match the 60601 value before 2005!!
- Therefore, we only need to look at the discontinuity aims.

One MSRE Solution for the Time Delay Issue

- The easiest solution to supply the Vision Cart on an Intuitive MSRE with a time-delay overcurrent protection is to fit two new radial single gang socket outlets protected by RCBOs supplied by the UPS.
- It does mean running four cables for L and N – two for each socket. The RCBOs can be fitted in the IPS rack.
- The SEB “clean earth” could be obtained from nearby IT sockets if low enough (0.1).
- The other two modules can simply plug into any existing Medical IT socket-outlets. The load of the robot arm and the patient cart are less than the Vision Cart .
- With a Medical TNS used for the Vision cart, the IPS load requirement is only then 20% Max - Total of 2 x 4A loads.


UPS
Medical IPS
Medical IPS
2 x Medical TNS RCBO
Time delay (k)
12 IT sockets
12 IT sockets
Single Gang for Vision Cart

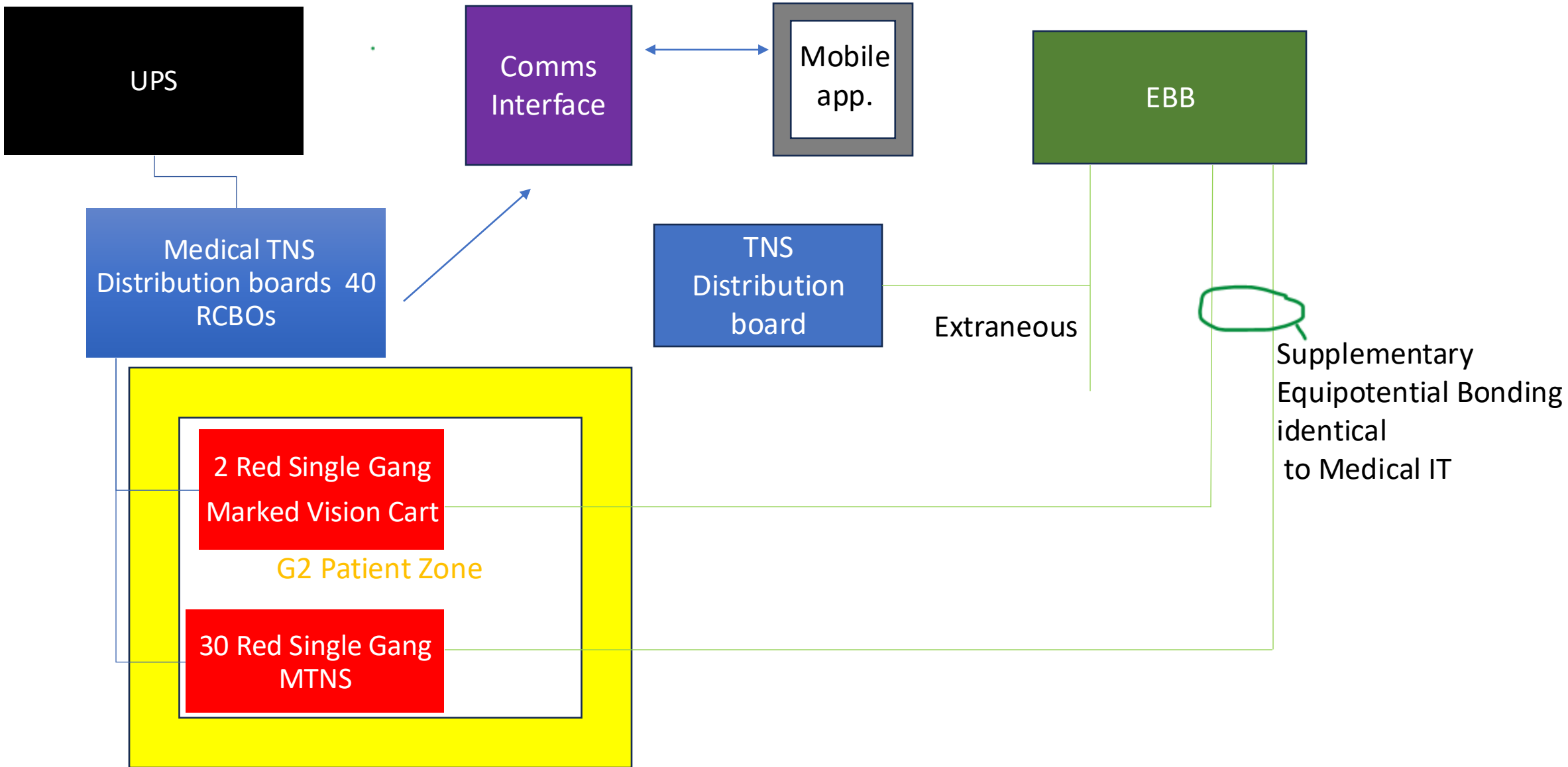
Wandsworth can supply Medical TNS socket outlets for the Vision Cart

Prototype Image

Medical TNS vs IT

- The extra radials solution for MSRE then led to the concept of Medical TNS

Medical TNS


UPS
Comms Interface
Mobile app.
EBB
Medical TNS Distribution boards 40 RCBOs
TNS Distribution board
Extraneous
Supplementary Equipotential Bonding identical to Medical IT
2 Red Single Gang Marked Vision Cart
G2 Patient Zone
30 Red Single Gang MTNS

Medical TNS vs IT

Why can it replace Medical IT?

- Medical IT circuits with an Isolated Power Supply (IPS) is to prevent the risk of discontinuity caused by any device on the same circuit, not any other circuit. Discontinuity is the electrical term used to describe an RCD or thermal trip activating and removing power from a circuit. This is evidenced from the IET Guidance note 7 *"The isolating transformer (BS7671 710.512.1.1) prevents the loss of a supply of **all** connected equipment when a first fault to earth occurs on a single item."*.
- This clearly has the same function as an RCB except it alarms and not trips and was introduced BEFORE RCBO circuits. It alarms at the pre 2005 device limit!! (0.5mA) – medical device earth leakage failure value is 5mA since 2005 (SFC = 10mA).
- It is important to understand that the isolated circuit does not limit patient leakage currents (microshock). Isolation is the technical means of being able to monitor the whole circuit from transient (spike) EARTH leakage currents when one device's insulation starts to fail.
- RCBO circuits can individually protect each device by having one RCBO per single gang socket.

Medical TNS Pros

- Significantly less cost than with Medical IT circuits. A rough estimate would be at least £10,000 less per Medical IT 10kVA circuit. Large loads would be easily tackled by MTNS individually protected RCBO circuits.
- The risk from one faulty device is limited to its own circuit
- Circuit loss can be easily identified by the neon or LED, which is much simpler than expensive IPS monitors, which require training. Simple socket indicators **do not require any training** as it is obvious that socket-outlet has no supply. If staff plug the medical equipment into another socket and it trips, it shows there is a fault and should be removed from service. There will be enough socket-outlets to be able to cope with a faulty device being plugged into more than one socket. If it was a transient fault, the equipment can continue to be used.
- MTNS can be installed around the patient zone, outside it on the nearby wall and if any other electrical equipment is mistakenly plugged into the MTNS, the only consequence will be extra load on the UPS during mains supply power failures. There should be enough UPS capacity to cope with most extra loads.
- Medical Surgical Robot Equipment (MSRE) that has a high load can be added to existing theatres by means of dedicated socket-outlets each protected by an RCBO. Some MSRE modules require a type k RCBO. A specific Medical TNS socket-outlet needs to be engraved accordingly with adjacent warning signs. These can be installed using an MTNS circuit if retro-fitting in an existing theatre.
- MTNS removes the need for the servicing costs of IPS controls.
- MTNS is easily understood by electricians and electrical designers.
- Companies like Siemens sell off the shelf switchgear monitoring . No need for central consoles when it can be sent to an app.
- https://www.siemens.com/global/en/products/energy/low-voltage/components/sentron-protection-devices/capable-circuit-protection-devices-communication.html

Medical TNS - Points to Watch

- Any sockets that require a type C or K characteristic RCBO will need to be under 0.1 ohms back to the EBB. Again, this is easily resolved with a larger equipotential bonding conductor just for that circuit. **This is for the designers.**
- Medical IT circuits - It may be argued that medical devices may have an intermittent earth fault but fitting MTNS with an RCBO means only the transient device will trip and they can plug it into another socket and if that trips, they should stop using it. It's that simple!!
- Can only be used with modern medical devices that are tested against the latest medical device standards (maybe less than 10 years old).
- One possible perceived con is that one medical device may suffer a transient trip and take out the radial RCBO but no other medical equipment is affected.
- Numerous conductors for many radial socket-outlets
- Highly populated distribution units to accommodate numerous RCBO's but it is easy to have numerous local distribution boards near to a bank of sockets such as pendants or pre-manufactured wall trunking that can also accommodate supplementary equipotential bonding connections points. These Distribution boards require easy access to reset.
- How do we mark each socket? Medical TNS? The red body colour is because it's from the UPS.

Next Steps

- Establish trial sites – this is because of discussions with me looking into publishing a peer reviewed paper.
- This needs top-down support to trial it to establish if the theory is correct and identify any issues.
- Trial sites is the answer.
- No finance needed as each trial G2 site will cost around £10k less (no IPS).
- Suggest ITU or room where discontinuity is the only risk (skin not penetrated).

Legal Discussion

- This design is not listed in the BS7671 guidance and will meet resistance because electricians and designers may not wish to digress from the guidance.
- Derogation is permitted with guidance provided a written risk assessment is undertaken in the form of a risk assessment.
- However, it will take significant time to change the UK guidance because there is no system to challenge the current system or allow for radical ideas like MTNS.
- It seems the way forward is to prove it works but to do so requires a sound prior risk assessment to prove a duty of care has been followed. I have produced a prior risk assessment. Any serious failings or deaths due to electrical issues are investigated by HSE or the Police to establish if there is evidence of a failing in the duty of care.
- However, this new circuit can only be commissioned if the healthcare provider undertakes a careful process by the Electrical Safety Group. This includes the clinical engineering team who collate all medical equipment used in that medical location and inform the ESG of the total number and load of all devices along with the time in hours required to be able to run solely on the UPS. Some UPS spare capacity is required. This practice should already be in place as per HTM 06-01 Chapter 3.
- The Electrical Safety Group need to include clinical staff to ensure the clinical risks are not affected. The ESG will also need to put a monitoring system in place as part of the monitoring of the new wiring system and can be used to evidence that MTNS is a cheaper, less complex and just as safe, if not safer, wiring system than Medical IT.

The End

medical.locations@icloud.com

Medical Locations on site training course is around 5 hours plus one hour in a group 2 location like a catheter lab.

Fixed price for unlimited numbers – I add travel costs onto the fixed price.

I can do it by Teams depending on numbers.