

Jennie - please confirm whether Biomedical Engineering will be taking over the responsibility for detaching and reinstalling the neurosuite table. Please also confirm support for the following.

Adrian - please advise me how you expect the B&I staff costs to be managed.

Horst - would you please make your expertise available for tomorrow evening from 18:00 to reattach the neuro table, or at least hand over the kit and documentation to me if either you are unavailable or it is agreed that BME will be looking after this from now on. I think that I'd appreciate you being around/on-the-phone never-the-less.

James - I believe that you're on-call Tuesday evening, so please assist or lead the reinstallation of the table or pass this information onto the person who is on-call and is capable of reinstalling the table or providing assistance to Horst.

Rhona - please provide access to the neurosuite after the last case on Tuesday as well as arrange for an End Of Day Check after the table has been reinstalled. I don't know who does the End Of Day Check, so please let me know who that is so that I can let that person know when we're finished. Please also let me know what lock up procedure you want me to follow if I need to be the last person to leave if I cannot leave the neurosuite theatre to the person doing the End Of Day Check.

Cameron - please confirm that the MRI imaging system will be tested on Wednesday morning prior to clinical use. Please also confirm that, as the MRI Safety Officer, you're satisfied with what we're doing.

There are two items left - access to a Wardsman and access to a trades person to assist with the installation. If you organised this in the past, then please do so again and let me know. I think that we will not need the trades person if we have Horst and James (or the on-call BME) working together on this with assistance from a Wardsman.

I'll be there for the entire process and will ensure handover to the person doing the End Of Day Check as well as contacting Rhona by SMS and Cameron via e-mail on completion.

I believe that we'll be finished with the reinstallation within two hours of being given the theatre, including the End Of Day Check. Please correct my estimate if you believe I am wrong.

Please call me on 6244 2256 if you have any queries. This number reaches me 24/7.

Cheers,

Sean

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Sean Geoghegan, PhD  
Chief Medical Physicist ACT Health ACT Australia  
p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
Care ----- Excellence ----- Collaboration ----- Integrity

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

sorry to take so long to get back to you.

I believe that it is safe to return the table to use on condition that the SOPs shown to us this morning by Rhona are followed by the Neurosuite staff. These SOPs cover testing that the room is clear of mobile magnetisable objects (covered in their End Of Day Check SOP) and determining that the image quality is clinically sufficient. I caught up with Cameron Robertson after our meeting this morning and he confirmed that they conduct image quality tests on the MRI before use.

**McClymont, Geoff**

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**From:** Van Lith, Martin  
**Sent:** Tuesday, 9 August 2011 2:16 PM  
**To:** Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Baker, Jennie  
**Subject:** Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan  
**Attachments:** Risk Plan 090811.docx

Hello

On Monday we met to discuss the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

Our task is to develop a risk management plan and identify any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

You raised many risks and issues before and during the meeting that are in the risk management plan. Attached is a DRAFT Risk Management Plan for your comment.

Please return your comments and updates to me on the attached in colour or track changes by COB Wednesday 10 August 2011.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
***Business and Infrastructure – committed to timely, responsive and client-focused services***  
Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
***Care Excellence Collaboration Integrity***

# DRAFT

## RISK MANAGEMENT PLAN

To be used for developing a risk management plan and identifying any risks that should be prioritised and / or escalated to the risk registers. These plans should be used for all activities, projects and business.

**Title (Project / Activity / Program):** Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH **File No:** .....

**Objective / Background:** Developing a risk management plan and identifying any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

**Prepared by:** Martin Van Lith, Phil Thorburn, Sean Geoghegan, Rhona JasonSmith, Horst Kirchner, James Cotterill, Rob Swain **Date:** 8 August 2011  
**Reviewed by:** (to be reviewed by Adrian Scott) **Date:** .....

| Risk No.                       | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Interchange IMRIS Table</b> |   |   |                    |                   |                    |                        |   |                                    |                                   |                            |
| 1                              | <p><b>What:</b><br/>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>There are many mechanical parts, such as screws, at the</li> </ul> | <ul style="list-style-type: none"> <li>A dedicated toolkit and parts list has been made for the interchange.</li> <li>A written procedure containing illustrative photographs has been drafted and tested.</li> <li>Workplace safety analysis has been made and issues addressed</li> <li>IMRIS has been consulted throughout the project.</li> <li>Cleaning operating procedure developed and tested.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Develop responsibility and training of staff for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Use a checklist for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Checklist to be used by the installation staff and a separate list by the spotter. Verify lists and sign off at the end of installation.</li> </ul> | Major                              | Unlikely                          | High                       |

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| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
|          | <p>base plate involved in the interchange of the IMRIS operating table.</p> <ul style="list-style-type: none"> <li>Responsibility and training of staff for the removal and re-installation not clear.</li> <li>The two hydraulic lines and connectors in the floor are thin walled solid metal tubing AND are flexed each time the table is moved. They are held in a flexed position under the cover plate. The stainless steel tubing will caseharden over time in the flexed (stressed) position and may crack. The hydraulic lines are also more vulnerable to damage if the table is moved on a regular basis.</li> <li>Every time the table is moved a small amount of oil leaks out and the possibility can arise where air bubbles may become trapped within the lines. The trapped air can then travel throughout the hydraulic circuit.</li> <li>Electrical wire connections need to be applied correctly.</li> <li>Potential for dirt and metal filings to remain in the operating theatre after the interchange</li> </ul> |  |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>Use one independent person as a spotter during removal and re-installation.</li> <li>Independent check each time of the re-installation of the IMRIS ORT100 Operating Table, e.g. mechanical, electrical, alignment, functions of the theatre table, verification of two checklists.</li> </ul> |                                    |                                   |                            |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect movement in the operating table.</li> <li>If the hydraulic lines did fail and there is a sudden loss of hydraulic pressure the effect 'could' be unwanted movement of the table bed and that 'could' create a life threatening situation.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Permanent loss of function for the patient unrelated to the underlying illness.</li> <li>Repairs to the hydraulic lines would be an expensive and lengthy process.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> <p><b>What:</b><br/>All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directory.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table is part of the MRI machine as an</li> </ul> | Not adequately addressed   | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>IMRIS re-install and certify the ORT100 operating table may reduce this liability</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
|          | <p>integrated and calibrated system in the Neurosuite.</p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>Health Directorate modifying the IMRIS operating table.</li> <li>The purpose of the IMRIS operating table has been changed from fixed equipment to interchangeable.</li> <li>The local IMRIS representative does <i>not</i> support the interchange of the IMRIS operating table and warns against such action.</li> <li>Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Legal liability</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> <p><b>What:</b></p> |  | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Seek legal opinion.</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?              | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|---|--------------------|-------------------|--------------------|------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
| 3        | <p>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Supplier knows that Health Directorate is interchanging the IMRIS Operating Table and advised against it.</li> <li>Health Directorate have chosen to use the IMRIS Operating Table outside its design parameter.</li> <li>Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Legal liability</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> <li>Reputation loss</li> </ul> | <ul style="list-style-type: none"> <li>Written operating procedure</li> </ul> | ble                | ble               |                    |                        |                 |                                    | e                                 |                            |
| 4        | <p><b>What:</b></p>  |   |                    |                   |                    |                        |                 |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 5        | <p>Interchanging the IMRIS operating table causes premature "wear and tear", as well as increases the chance for error.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Written procedure for interchanging the IMRIS operating table not being followed.</li> <li>Moving the operating table on a regular basis increases wear and tear on the connecting parts.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Extra costs</li> <li>Interference with theatre booking schedule</li> </ul> | <ul style="list-style-type: none"> <li>Two people installing and one person observing.</li> <li>Final check and signoff by an independent person following checking the reinstallation.</li> <li>Written procedures for cleaning</li> <li>Magnet roller check for metals</li> </ul> | Major              | Probable          | High               |                        | <ul style="list-style-type: none"> <li>Ensure that the metal cover plate has an operating theatre table or other large equipment located over it at all times and does not present a trip hazard.</li> </ul> | Major                              | Unlikely                          | High                       |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 6        | <ul style="list-style-type: none"> <li>The 'hump' in the metal cover plate presents a hazard if the operating table is moved with a patient.</li> <li>Busy work environment</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Damage to staff or patients.</li> <li>Costs</li> </ul> <p><b>What:</b><br/>Present lighting pendants will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The theatre lights are considered not as effective when used anywhere else that where the IMRIS Operating Table is located.</li> <li>The Jackson Spinal operating theatre table is longer than a normal operating table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Inadequate lighting of the surgical site.</li> <li>Injury to patient</li> </ul> |  | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Modifying operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding exiting theatre light.</li> </ul> | Major                              | Rare                              | Medium                     |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments                                    | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 7        | <ul style="list-style-type: none"> <li>Modification of the operating theatre light required for the MRI Neurosuite.</li> <li>Extra costs</li> </ul> <p>What:<br/>Due to:<br/>Resulting in:</p> | <ul style="list-style-type: none"> <li></li> </ul>               |                    |                   |                    |                        | <ul style="list-style-type: none"> <li></li> </ul> |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 1        | <p><b>What:</b><br/>The MRI Neurosuite not being fully utilised for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The full MRI Neurosuite being presently utilised for approx. 12 cases per year.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table but does not have an interchangeable table top.</li> <li>Surgical staff consider that the IMRIS Operating Table is not wide enough (606.5 mm) for general surgery and limited in its use, such as in spinal surgery.</li> <li>The IMRIS ORT 100 Operating Table with the back section removed and the body rotated 180 degrees not allowing enough room for the extra long Jackson Spinal operating table.</li> <li>Surgical staff not satisfied with using the remaining part of the IMRIS Operating Table top for holding instruments and consumables during surgery.</li> </ul> | <ul style="list-style-type: none"> <li>IMRIS claim that the ORT-100 operating table was designed to cater for the vast majority of surgical procedures, however admit that certain specialised procedures, such as spinal surgery, are best performed on an alternate table.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table with a wide range of movements and functionality, but essentially it's a standard operating table that is MR compatible.</li> <li>The back section of the ORT-100 table is radiolucent and therefore X-ray compatible.</li> <li>The ORT-100 table has a removable back section and the body rotates 180 degrees, which is useful if an alternate operating table is used alongside.</li> <li>There is an optional table top for use with neonates.</li> <li>The MRI Neurosuite is very</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Rotate the IMRIS ORT 100 Operating Table into the least obstructive position, remove the backrest and cover/protect the table top from liquid ingress and damage.</li> <li>Do not use the Jackson Spinal operating theatre table in this operating theatre.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

Leave IMRIS Table in Position

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
| 2        | <ul style="list-style-type: none"> <li>This operating theatre is considered by surgical staff as a neurosuite and not for other surgical procedures that the IMRIS Operating Table would facilitate.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Less surgical treatments</li> <li>Loss of income</li> <li>Not meeting surgical KPIs</li> <li>Loss of reputation</li> </ul> <p><b>What:</b><br/><b>Due to:</b><br/><b>Resulting in:</b></p> | <p>large, there appears to be adequate room for an alternative normal sized operating table to be used alongside the ORT100 table.</p> <ul style="list-style-type: none"> <li>IMRIS reported that other hospitals approach the problem by leaving the IMRIS operating table fixed in situ and simply wheel in an alternate table and operate it along-side the IMRIS table.</li> </ul> |                    |                   |                    |                           |                 |                                    |                                   |                            |



| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 1        | <p><b>What:</b><br/>Shortage of operating theatres at TCH.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Incompatible operating theatres to the requirements of the surgeons / theatre staff.</li> <li>Limited use of old theatre pendants, theatre lights and communication cables.</li> <li>The MRI Neurosuite is required to be left "Ready To Scan" at the end of each day.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Backlog in surgery cases.</li> <li>No spare operating theatre for shutdown of other theatres to allow replacing the theatre pendants, lights and cabling work; they require be updating and making safer. Estimated to take 16 working days shutdown for each two operating theatres to do the updating work. It would require 4 (set of 2 theatres) x 16 = 64 working days to complete this previously planned work.</li> </ul> | <ul style="list-style-type: none"> <li>The two Jackson Spinal operating tables are presently used in the other operating theatres.</li> <li>Daily operating theatre scheduling with little or no spare capacity.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Upgrade the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed.</li> <li>Negotiate agreement with other surgical service providers to facilitate surgery during the remediation work, e.g. Royal Darwin Hospital used portable operating theatres installed on-site from the Defence Department.</li> <li>Re-evaluate interchanging the IMRIS Operating Table after the operating theatre pendants have been replaced in all the other theatres.</li> </ul> | Moderate                           | Unlikely                          | MEDIUM                     |

Incidental Issues

|                 |   |   |   |                           |                          |                           |                                  |   |   |  |                                   |
|-----------------|---|---|---|---------------------------|--------------------------|---------------------------|----------------------------------|---|---|--|-----------------------------------|
| <b>Risk No.</b> | 2 | <b>Risk Description</b><br>What can happen and how  | <b>Current Controls</b><br>What do you already do to mitigate the risk? | <b>Consequence Rating</b> | <b>Likelihood Rating</b> | <b>Current Risk Level</b> | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b>  | <b>Consequence Rating after Treatment</b> | <b>Likelihood Rating after Treatment</b> | <b>Risk Level after Treatment</b> |
|                 |   | <p><b>What:</b><br/>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Ferrous objects attracted to the magnet.</li> <li>• Leaving small metal items or fragments after surgery in the MRI Neurosuite that will be attracted to the magnet when it starts to function, such as pins, screws, metal thread and fragments from implants.</li> <li>• Likelihood of occurrence when this theatre is used for some other surgical procedures, e.g. implants, orthopaedic.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unclear images.</li> <li>• Injury to staff</li> </ul> |   | Moderate                  | Possible                 | Medium                    |                                  | Conduct a metal sweep with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal. | Moderate                                  | Unlikely                                 | Medium                            |

|                 |   |  |   |                           |                          |                           |                                  |                        |   |  |                                   |
|-----------------|---|--|---|---------------------------|--------------------------|---------------------------|----------------------------------|------------------------|---|--|-----------------------------------|
| <b>Risk No.</b> | 3 | <b>Risk Description</b><br>What can happen and how     | <b>Current Controls</b><br>What do you already do to mitigate the risk? | <b>Consequence Rating</b> | <b>Likelihood Rating</b> | <b>Current Risk Level</b> | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b> | <b>Consequence Rating after Treatment</b> | <b>Likelihood Rating after Treatment</b> | <b>Risk Level after Treatment</b> |
|                 |   | <b>What:</b><br><b>Due to:</b><br><b>Resulting in:</b> |   |                           |                          |                           |                                  |                        |   |  |                                   |

**McClymont, Geoff**

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**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:46 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: Neuro Theatre Table

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**From:** Baker, Jennie  
**Sent:** Tuesday, 9 August 2011 2:31 PM  
**To:** Scott, Adrian  
**Cc:** Geoghegan, Sean; Thorburn, Phillip  
**Subject:** Neuro Theatre Table

Hi Adrian,

As directed, this afternoon the BME team will and Horst will reinstall the neuro theatre table.

After this installation under the supervision of Horst, the BME staff will take over responsibility for the installation of the table.

The BME staff retain concerns about responsibility for these actions should there be any resultant injury to staff or patients from the utilisation of this system being used in a manner for which it was not intended and the fact that they could be construed to be the "manufacturer".

I have explained that you have undertaken a risk assessment and sought advice about the risks inherent in the process and have requested them to proceed. They are proceeding on the understanding that the responsibility and accountability for this move remains with you.

Regards.

Jennie

**McClymont, Geoff**

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**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:57 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: The Neuro Theatre Table

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**From:** Kirchner, Horst  
**Sent:** Tuesday, 9 August 2011 4:04 PM  
**To:** Geoghegan, Sean; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron; Sommariva, Maurice  
**Cc:** Van Lith, Martin; Thorburn, Phillip; Swain, Rob  
**Subject:** RE: The Neuro Theatre Table

Thank you all, see you then

cheers

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363  
mob. [REDACTED]

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Care Excellence Collaboration Integrity*



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**From:** Geoghegan, Sean  
**Sent:** Tuesday, 9 August 2011 4:03 PM  
**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron; Sommariva, Maurice  
**Cc:** Van Lith, Martin; Thorburn, Phillip; Swain, Rob  
**Subject:** RE: The Neuro Theatre Table

Hi all,

As just confirmed with Rhona and Horst, Horst together with James and Maurice from Biomedical Engineering and myself from Medical Physics will conduct the table installation at 6:00 tomorrow morning.

Cheers,

Sean  
**Sean Geoghegan**  
Chief Medical Physicist Medical Physics and Medical Technology Systems  
Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Kirchner, Horst  
**Sent:** Tuesday, 9 August 2011 1:27 PM  
**To:** Geoghegan, Sean; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron

**Cc:** Van Lith, Martin  
**Subject:** RE: The Neuro Theatre Table

Sean,  
I would prefer to come in early tomorrow (6am or so!) to assist in the bed install.  
(I have an engagement most Tuesday evenings)  
Unless the theatre is free around 3pm today. (Rhona will let me know)

cheers

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363  
mob [REDACTED]

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 10:17 PM  
**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron  
**Subject:** FW: The Neuro Theatre Table

Hi Jennie, Adrian, Horst, James, Rhona and Cameron,

with regard to the reinstallation of the neurosuite table on the evening of Tuesday 9 August in preparation for a case on the following Wednesday morning:

Jennie - please confirm whether Biomedical Engineering will be taking over the responsibility for detaching and reinstalling the neurosuite table. Please also confirm support for the following.

Adrian - please advise me how you expect the B&I staff costs to be managed.

Horst - would you please make your expertise available for tomorrow evening from 18:00 to reattach the neuro table, or at least hand over the kit and documentation to me if either you are unavailable or it is agreed that BME will be looking after this from now on. I think that I'd appreciate you being around/on-the-phone never-the-less.

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Please call me on 6244 2256 if you have any queries. This number reaches me 24/7.

Cheers,

Sean

Sean Geoghegan, PhD  
Chief Medical Physicist ACT Health ACT Australia  
p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
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---

**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

sorry to take so long to get back to you.

I believe that it is safe to return the table to use on condition that the SOPs shown to us this morning by Rhona are followed by the Neurosuite staff. These SOPs cover testing that the room is clear of mobile magnetisable objects (covered in their End Of Day Check SOP) and determining that the image quality is clinically sufficient. I caught up with Cameron Robertson after our meeting this morning and he confirmed that they conduct image quality tests on the MRI before use.

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Cheers,

Sean

---

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 09:46

**To:** Baker, Jennie; Thorburn, Phillip  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

I'll provide you with an opinion after our meeting with Rhona this morning at 10:00.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Baker, Jennie

**Sent:** Monday, 8 August 2011 9:44 AM

**To:** Geoghegan, Sean; Thorburn, Phillip

**Subject:** The Neuro Theatre Table

Hi Gentlemen,

Adrian has informed me that we will receive a request to reinstall the MRI table for a case on Wednesday.

In your professional opinions do you consider it safe for use as a MRI/Neuro table after installation by the Facilities/BME team?

Jennie

**Jennie Baker**

Director Business Support

ACT Health

Phone 02 6244 3045

Mobile [REDACTED]

[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)



**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:56 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: The Neuro Theatre Table

---

**From:** [REDACTED]  
**Sent:** Tuesday, 9 August 2011 4:13 PM  
**To:** Geoghegan, Sean  
**Subject:** RE: The Neuro Theatre Table

Great I see you tomorrow

---

**From:** Geoghegan, Sean  
**Sent:** Tuesday, 9 August 2011 4:08 PM  
**To:** [REDACTED]  
**Cc:** Cotterill, James; Williams, Horace; Baker, Jennie; Hallberg, Erik  
**Subject:** RE: The Neuro Theatre Table

Hi [REDACTED]

I've just got to this now. As discussed between ourselves about 30 minutes ago, we'll now be performing this task at 6:00 tomorrow morning with Horst and James. I understand that Horst will do the installation with assistance from yourself.

I also have reservations with the procedure – Martin Van Lith, Rob Swain, Phil Thorburn and myself are undertaking a risk analysis on removing and reinstalling the iMRI table which is due on Adrian Scott's desk this Friday afternoon.

I believe that Jennie is chasing up the disclaimer from Adrian for us. I agree that your request for this is more than reasonable.

Cheers,

Sean  
**Sean Geoghegan**  
 Chief Medical Physicist Medical Physics and Medical Technology Systems  
 Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**From:** [REDACTED]  
**Sent:** Tuesday, 9 August 2011 2:51 PM  
**To:** Geoghegan, Sean  
**Cc:** Cotterill, James; Williams, Horace; Baker, Jennie; Hallberg, Erik  
**Subject:** RE: The Neuro Theatre Table

Hi Sean,

Could you please explain what my role will be this afternoon, as I haven't been able to extract from the previous emails what Biomedical Engineering/myself is supposed to be doing in this occasion. My understanding is that in future, we are being asked to carry out the actual reinstallation/removal of the theatre table?

I am available this afternoon at 16:00 onwards as the on-call Biomedical Engineer. I have reservations as to actually participate in the installing of the table since I believe that removing/installing is against manufacturers recommendations, however I will attend to help clarify and learn about the procedure.

In future, the team members(Horace, James, Erik) and myself will perform this task, only after receiving an appropriate disclaimer where the safety and technical issues that have been raised as probable liability become fully the responsibility of those requesting this procedure, thus removing any fault from carrying out this procedure as I feel that in the event of equipment malfunction the person carrying this installation/removal would be blamed. I'm sure that you can appreciate that it's a reasonable request, that if something goes against the technical advice you are offering then it should become that someone else's responsibility to bear that risk.

Cheers

---

**From:** Geoghegan, Sean  
**Sent:** Tuesday, 9 August 2011 1:23 PM  
**To:** Kirchner, Horst; Sommariva, Maurice  
**Cc:** Baker, Jennie; Thorburn, Phillip; Cotterill, James  
**Subject:** FW: The Neuro Theatre Table

Hi Horst and [REDACTED]

It looks like we'll be on from 16:00 for the iMRI table move this afternoon. Are you able to make it then?

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**From:** JasonSmith, Rhona  
**Sent:** Tuesday, 9 August 2011 12:53 PM  
**To:** Geoghegan, Sean  
**Subject:** RE: The Neuro Theatre Table

Hi Sean

As per our phone conversation, I am anticipating that we will be able to have access to the Neuro Suite from around 4pm, and I will phone you if that time alters. I have planned for an In-between clean to be undertaken at the end of the 2<sup>nd</sup> case so that the environment will be safe for you and your colleagues to work in. Once you have completed the installation of the table an End-of-Day clean will be undertaken and all the associated checks carried out as per the SOPs. Angela Goodridge is the Patient Flow CNC in-charge of the unit this evening and she is the person to contact when the works have been completed. You will not be required to 'lock up' after you finish, as there will still be a body of clinical re-stocking and setting up to be completed by the nursing staff in preparation for the next day.

Thank you

Rhona

Rhona JasonSmith  
 Assistant Director of Nursing Perioperative Services  
 The Canberra Hospital

ph (02) 62443051  
fx (020) 6244 3348

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---

**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 10:17 PM  
**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron  
**Subject:** FW: The Neuro Theatre Table

Hi Jennie, Adrian, Horst, James, Rhona and Cameron,

with regard to the reinstallation of the neurosuite table on the evening of Tuesday 9 August in preparation for a case on the following Wednesday morning:

Jennie - please confirm whether Biomedical Engineering will be taking over the responsibility for detaching and reinstalling the neurosuite table. Please also confirm support for the following.

Adrian - please advise me how you expect the B&I staff costs to be managed.

Horst - would you please make your expertise available for tomorrow evening from 18:00 to reattach the neuro table, or at least hand over the kit and documentation to me if either you are unavailable or it is agreed that BME will be looking after this from now on. I think that I'd appreciate you being around/on-the-phone never-the-less.

James - I believe that you're on-call Tuesday evening, so please assist or lead the reinstallation of the table or pass this information onto the person who is on-call and is capable of reinstalling the table or providing assistance to Horst.

Rhona - please provide access to the neurosuite after the last case on Tuesday as well as arrange for an End Of Day Check after the table has been reinstalled. I don't know who does the End Of Day Check, so please let me know who that is so that I can let that person know when we're finished. Please also let me know what lock up procedure you want me to follow if I need to be the last person to leave if I cannot leave the neurosuite theatre to the person doing the End Of Day Check.

Cameron - please confirm that the MRI imaging system will be tested on Wednesday morning prior to clinical use. Please also confirm that, as the MRI Safety Officer, you're satisfied with what we're doing.

There are two items left - access to a Wardsman and access to a trades person to assist with the installation. If you organised this in the past, then please do so again and let me know. I think that we will not need the trades person if we have Horst and James (or the on-call BME) working together on this with assistance from a Wardsman.

I'll be there for the entire process and will ensure handover to the person doing the End Of Day Check as well as contacting Rhona by SMS and Cameron via e-mail on completion.

I believe that we'll be finished with the reinstallation within two hours of being given the theatre, including the End Of Day Check. Please correct my estimate if you believe I am wrong.

Please call me on 6244 2256 if you have any queries. This number reaches me 24/7.

Cheers,

Sean

---

Sean Geoghegan, PhD  
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p: +61 2 6244 2256    f: +61 2 6244 2276    m: [REDACTED]  
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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

sorry to take so long to get back to you.

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The single highest likelihood risk is the risk that the hydraulics will fail. This will eventually happen with work hardening and fatigue of the steel hydraulic connecting tubes at the base of the table stand that protrude from the floor. We probably have many cycles of detachment and reattachment before failure occurs. I believe that a practical alternative to repeatedly detaching and reattaching the hydraulics with the current configuration can be devised in the short to medium term - this will be addressed as part of our risk assessment being developed between Martin Van Lith, Rob Swain, Phil Thorburn and myself.

Tomorrow, the MRI neuro table will need to be reinstalled for a case from 8:00 on Wednesday morning. We'll get the theatre after the last case of the day at approximately 18:00 on Tuesday. We'll need to arrange staff to install the table, and check the installation. I'll liaise with James, Horst and Rhona to make it happen.

I have a full day of meetings tomorrow, but will keep an eye on my e-mails and make sure that we have all arranged before 18:00 tomorrow.

Cheers,

Sean

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 09:46  
**To:** Baker, Jennie; Thorburn, Phillip  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

I'll provide you with an opinion after our meeting with Rhona this morning at 10:00.

Cheers,

Sean

**Sean Geoghegan**  
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 Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**From:** Baker, Jennie  
**Sent:** Monday, 8 August 2011 9:44 AM  
**To:** Geoghegan, Sean; Thorburn, Phillip  
**Subject:** The Neuro Theatre Table

Hi Gentlemen,

Adrian has informed me that we will receive a request to reinstall the MRI table for a case on Wednesday.

In your professional opinions do you consider it safe for use as a MRI/Neuro table after installation by the Facilities/BME team?

Jennie

**Jennie Baker**  
Director Business Support  
ACT Health

Phone 02 6244 3045

Mobile [REDACTED]

[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)

Folio 480 - 481

Exempt under Section 36 of the Freedom of Information Act

**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:56 PM  
**To:** McClymont, Geoff  
**Subject:** IMRI FOI - FW: The Neuro Theatre Table  
**Attachments:** IMRIS REMOVAL OF BED 080711.doc; Material list for Imris Table.docx; Procedure for removing the IMRIS OR Table at Canberra Hospital.pdf; Tool Kit for IMRIS removal.doc

---

**From:** Kirchner, Horst  
**Sent:** Wednesday, 10 August 2011 10:30 AM  
**To:** Geoghegan, Sean  
**Subject:** RE: The Neuro Theatre Table

Sean, for your records

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
3ldg. 6, L3, TCH  
62050363  
mob. [REDACTED]

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*Care Excellence Collaboration Integrity*



---


**From:** Geoghegan, Sean  
**Sent:** Tuesday, 9 August 2011 4:03 PM  
**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron; Sommariva, Maurice  
**Cc:** Van Lith, Martin; Thorburn, Phillip; Swain, Rob  
**Subject:** RE: The Neuro Theatre Table

Hi all,

As just confirmed with Rhona and Horst, Horst together with James and Maurice from Biomedical Engineering and myself from Medical Physics will conduct the table installation at 6:00 tomorrow morning.

Cheers,

Sean  
**Sean Geoghegan**  
Chief Medical Physicist Medical Physics and Medical Technology Systems  
Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)

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---

**From:** Kirchner, Horst  
**Sent:** Tuesday, 9 August 2011 1:27 PM  
**To:** Geoghegan, Sean; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron  
**Cc:** Van Lith, Martin  
**Subject:** RE: The Neuro Theatre Table

Sean,

I would prefer to come in early tomorrow (6am or so!) to assist in the bed install.

(I have an engagement most Tuesday evenings)

Unless the theatre is free around 3pm today. (Rhona will let me know)

cheers

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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**From:** Geoghegan, Sean

**Sent:** Monday, 8 August 2011 10:17 PM

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**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
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Cheers,

Sean

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p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 09:46  
**To:** Baker, Jennie; Thorburn, Phillip  
**Subject:** RE: The Neuro Theatre Table

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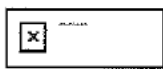
Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Baker, Jennie

**Sent:** Monday, 8 August 2011 9:44 AM

**To:** Geoghegan, Sean; Thorburn, Phillip

**Subject:** The Neuro Theatre Table

Hi Gentlemen,

Adrian has informed me that we will receive a request to reinstall the MRI table for a case on Wednesday.

In your professional opinions do you consider it safe for use as a MRI/Neuro table after installation by the Facilities/BME team?

Jennie

**Jennie Baker**

Director Business Support

ACT Health

Phone 02 6244 3045

Mobile [REDACTED]

[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)

## NOTES

### IMRIS Removal of Bed Run-through

08 July 2011

**Present:** ©Rhona JasonSmith, Elina Black, Cameron Robertson, Shane Guy, Bobby Tasic, Phillipa Keating, Horst Kirchner – Keith & John, Ben Lollback, Rochelle Woolf  
**Apologies:** Rhonda Hosking, Wendy Beckingham, Steve Saker  
**Minutes:** Elina Black

#### 1. Process as per instructions

- IMRIS bed is brought out via a dedicated manual trolley to OR14
- Imris has supplied stainless steel caps that will not interfere with scans

#### 2. Issues Arising

- Washers need to be put on – what type of material are they made out of? – (rubber/metal?)
- Trolley is a little hard to manoeuvre to get into perfect position over bolts
- No vision around trolley
- Who will be responsible for removing and reattaching the bed?
- Where will the trolley be stored out side of the OR?
- “Design Fault” – movement of bed at the base – replacement part is coming (Horst)
- Possible thread damage to bolts – be mindful when re attaching bolts

#### 3. Recommendations

- Tools for IMRIS Bed Kit
  - Correct size spanner
  - Hammer
  - Alan Keys
  - File for thread on bolts
- Line-marking to the floor – similar to the black & cold strips on the trolley will help with alignment over bolts
- Plastic caps/tubing to be placed over bolts to prevent damage
- Rubber casing to be removed from floor & attached to base of bed instead (easier to adjust trolley over bolts)
- One person to ensure all hands are clear before lowering bed

#### 4. SOP/SWP

- Crush Injury Prevention – SWP/SOP
- BioMedical Tech, Electrician & Fitter require training when the Imris table is being installed

**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:56 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: The Neuro Theatre Table  
**Attachments:** Refitting Imris Operating Table.doc

---

**From:** Kirchner, Horst  
**Sent:** Wednesday, 10 August 2011 10:40 AM  
**To:** Geoghegan, Sean  
**Subject:** RE: The Neuro Theatre Table

Sean , more docs relevant to IMRIS table, to much for 1 email. And two emails form IMRIS,

Lindley, thanks for the update.

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363

**From:** [REDACTED]  
**Sent:** Thursday, 23 June 2011 10:36 PM  
**To:** Kirchner, Horst  
**Subject:** RE:

Horst:

We are in the process of releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock. The parts are going into production next week, so I will soon have a date for the delivery of the parts to my group for implementation. The updates will be scheduled with each customer once I have the delivery dates for the parts.

Best Regards,

[REDACTED]

[REDACTED]

**From:** Kirchner, Horst [<mailto:Horst.Kirchner@act.gov.au>]  
**Sent:** June-22-11 9:59 PM  
**To:** [REDACTED]  
**Subject:**

[REDACTED] we are taking the table of the floor today, I noticed that the locking pin (picture) was quite loose, this does not seem right, as the table moves when locked?.

cheers

*Horst Kirchner*

Hi Horst:

The IMRIS bed can be lifted by the rails, however a locking device needs to be installed first to prevent damage to the hydraulic system. The lock is easy to install and consists of 3 parts. Two parts that hold the lifting pedestal in the

lowest position, and the third that locks the rotation of the table. We are shipping those parts to you by courier today attention to Cameron Robertson at the hospital (see attached FedEx detail).

Attached is the procedure for removal of the OR Table.

There are calibration steps that must be followed when the table is reinstalled. This is necessary to ensure the alignment of the table with the magnet, and to ensure that all of the air is bled from the system. IMRIS will be required to return to the site at the time of reinstallation to ensure that the system meets all requirements. Please also note that the table is not designed for repeated removal and reinstallation, and if this is done more than once, it could result in problems with seizing of the fasteners, or hydraulic leaks requiring replacement of some hydraulic fittings.

On additional and VERY IMPORTANT step that must be taken if the OR Table is going to be removed. The control for the large sliding doors must be locked and the key removed and locked away somewhere safe to prevent anyone from moving the magnet into the OR. If someone was to bring the magnet into the OR with the wrong OR Table installed the OR table could be sucked into the magnet. The control panel has a key switch on it for locking the doors.

Much of our preventive maintenance routine relies on interaction between the system and the OR Table so without the table installed, we will be unable to fully complete the PM procedures.

Finally, please note that IMRIS will not assume any liability for issues related to safety or functionality in the OR as specifically related to the environment created through the removal of our OR Table. Should you have any further questions or concerns, please feel free to contact me as per below.

Best Regards,

[Redacted signature]

**From:** [Redacted]  
**Sent:** May-29-11 10:40 PM  
**To:** [Redacted]  
**Subject:** Fw: IMRIS bed  
Hi [Redacted]

Another query from Canberra.

regards,

[Redacted signature]

**From:** Kirchner, Horst [<mailto:Horst.Kirchner@act.gov.au>]  
**Sent:** Sunday, May 29, 2011 08:21 PM  
**To:** [Redacted]  
**Cc:** [Redacted]  
**Subject:** IMRIS bed

[Redacted] I forgot to ask,

If we lift the bed can we lift at the table side rails, or should we try to clamp the column. We do want to lift the unit as one piece.

regards

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363  
mob [Redacted]

*Horst Kirchner*

Business & Infrastructure

Strategic Support

Bldg. 6, L3, TCH

62050363

mob [REDACTED]

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---

**From:** Geoghegan, Sean

**Sent:** Tuesday, 9 August 2011 4:03 PM

**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron; Sommariva, Maurice

**Cc:** Van Lith, Martin; Thorburn, Phillip; Swain, Rob

**Subject:** RE: The Neuro Theatre Table

Hi all,

As just confirmed with Rhona and Horst, Horst together with James and Maurice from Biomedical Engineering and myself from Medical Physics will conduct the table installation at 6:00 tomorrow morning.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**rom:** Kirchner, Horst

**Sent:** Tuesday, 9 August 2011 1:27 PM

**To:** Geoghegan, Sean; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron

**Cc:** Van Lith, Martin

**Subject:** RE: The Neuro Theatre Table

Sean,

I would prefer to come in early tomorrow (6am or so!) to assist in the bed install.

(I have an engagement most Tuesday evenings)

Unless the theatre is free around 3pm today. (Rhona will let me know)

cheers

*Horst Kirchner*

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62050363

mob. [REDACTED]

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**From:** Geoghegan, Sean

**Sent:** Monday, 8 August 2011 10:17 PM

**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron

**Subject:** FW: The Neuro Theatre Table

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Jennie - please confirm whether Biomedical Engineering will be taking over the responsibility for detaching and reinstalling the neurosuite table. Please also confirm support for the following.

Adrian - please advise me how you expect the B&I staff costs to be managed.

Horst - would you please make your expertise available for tomorrow evening from 18:00 to reattach the neuro table, or at least hand over the kit and documentation to me if either you are unavailable or it is agreed that BME will be looking after this from now on. I think that I'd appreciate you being around/on-the-phone never-the-less.

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Cameron - please confirm that the MRI imaging system will be tested on Wednesday morning prior to clinical use. Please also confirm that, as the MRI Safety Officer, you're satisfied with what we're doing.

There are two items left - access to a Wardsman and access to a trades person to assist with the installation. If you organised this in the past, then please do so again and let me know. I think that we will not need the trades person if we have Horst and James (or the on-call BME) working together on this with assistance from a Wardsman.

I'll be there for the entire process and will ensure handover to the person doing the End Of Day Check as well as contacting Rhona by SMS and Cameron via e-mail on completion.

I believe that we'll be finished with the reinstallation within two hours of being given the theatre, including the End Of Day Check. Please correct my estimate if you believe I am wrong.

Please call me on 6244 2256 if you have any queries. This number reaches me 24/7.

Cheers,

Sean

Sean Geoghegan, PhD

Chief Medical Physicist ACT Health ACT Australia

p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

sorry to take so long to get back to you.

I believe that it is safe to return the table to use on condition that the SOPs shown to us this morning by Rhona are followed by the Neurosuite staff. These SOPs cover testing that the room is clear of mobile magnetisable objects (covered in their End Of Day Check SOP) and determining that the image quality is clinically sufficient. I caught up with Cameron Robertson after our meeting this morning and he confirmed that they conduct image quality tests on the MRI before use.

The single highest likelihood risk is the risk that the hydraulics will fail. This will eventually happen with work hardening and fatigue of the steel hydraulic connecting tubes at the base of the table stand that protrude from the floor. We probably have many cycles of detachment and reattachment before failure occurs. I believe that a practical alternative to repeatedly detaching and reattaching the hydraulics with the current configuration can be devised in the short to medium term - this will be addressed as part of our risk assessment being developed between Martin Van Lith, Rob Swain, Phil Thorburn and myself.

Tomorrow, the MRI neuro table will need to be reinstalled for a case from 8:00 on Wednesday morning. We'll get the theatre after the last case of the day at approximately 18:00 on Tuesday. We'll need to arrange staff to install the table, and check the installation. I'll liaise with James, Horst and Rhona to make it happen.

I have a full day of meetings tomorrow, but will keep an eye on my e-mails and make sure that we have all arranged before 18:00 tomorrow.

Cheers,

Sean

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Sean Geoghegan, PhD  
Chief Medical Physicist ACT Health ACT Australia  
p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
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---

**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 09:46  
**To:** Baker, Jennie; Thorburn, Phillip  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

I'll provide you with an opinion after our meeting with Rhona this morning at 10:00.

Cheers,

Sean

**Sean Geoghegan**  
Chief Medical Physicist Medical Physics and Medical Technology Systems  
Phone: 6244 2256 | Mobile: [REDACTED] | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**From:** Baker, Jennie  
**Sent:** Monday, 8 August 2011 9:44 AM  
**To:** Geoghegan, Sean; Thorburn, Phillip  
**Subject:** The Neuro Theatre Table

Hi Gentlemen,

Adrian has informed me that we will receive a request to reinstall the MRI table for a case on Wednesday.

In your professional opinions do you consider it safe for use as a MRI/Neuro table after installation by the Facilities/BME team?

Jennie

**Jennie Baker**  
Director Business Support  
ACT Health

Phone 02 6244 3045  
Mobile [REDACTED]

[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)

## Refitting Imris Operating Table.



**A guide to installing the IMRIS ORT 100;  
Personal must be trained for this operation.**

- Allow 30 minutes to remove the table.
- Allow 1 hour for the re-fitting.
- Follow the instructions, and use care when lowering the table, there are plastic tubes in the tool kit, to cover the floor mounting studs.
- Clean up after the installation.
- Check that all tools and fittings (bolts, screws, nuts, washers, grommets etc.) are bagged and placed in the tool bag.



1; Check with Clinical staff, that theatre is ready for installation.



2; Wheel the table & trolley into MRI theatre 14, **Check that power to table is isolated.**

**The key for the Distribution Board is in control room Key Cabinet**



3; Remove stainless steel cover on floor; do not disturb the packing strips or packing filler.



Note, Use the cover as a tray to hold all the nuts, screws and tools





4; Position the bed base over the 4 studs, the studs are numbered as are the holes, the bed has a folding, head attachment, and this must face the Magnet room.



**Do not move the packing strips, fit plastic tubes over studs to reduce chance of damage by bed base.**

5; Position the trolley with table over the base area. This will require a spotter & driver, align the bed base with the edges of packing. Lower the bed onto the floor, do not remove the frame until the bed is sitting flat. **!!!!. Caution keep hands clear when lowering table**





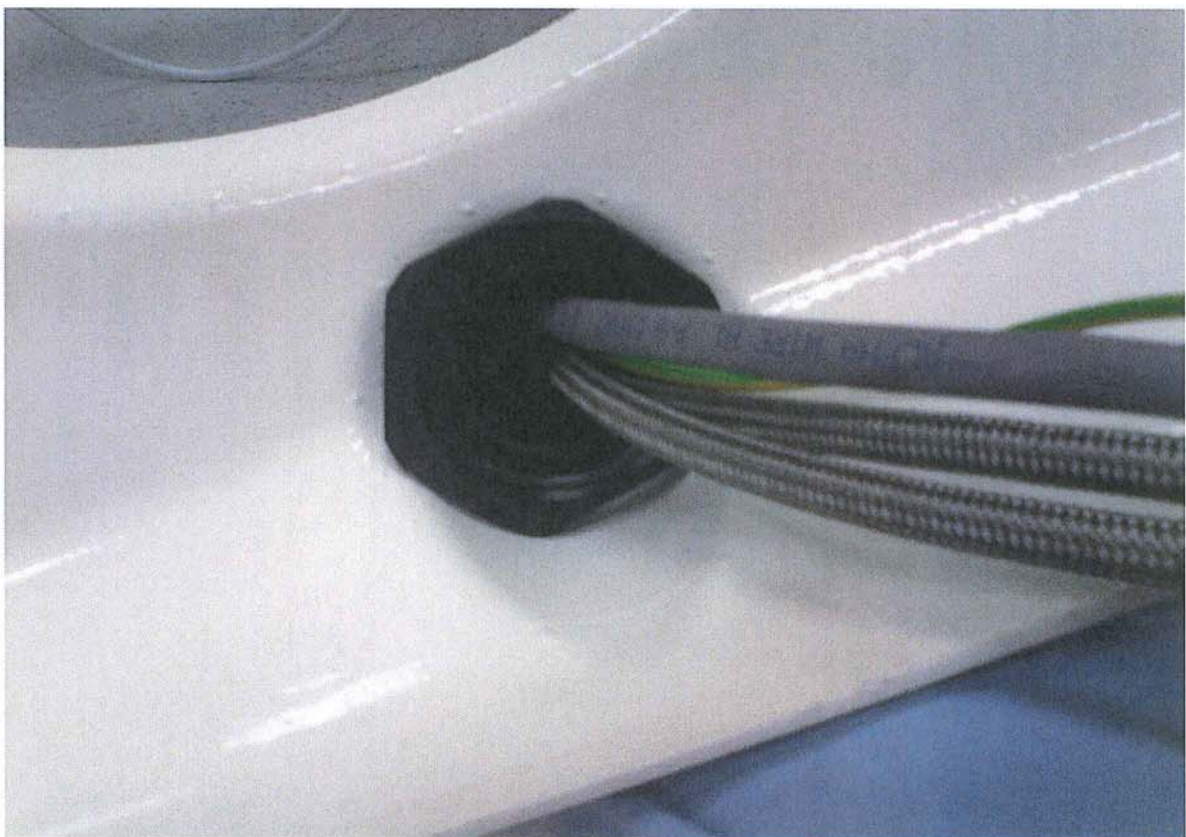
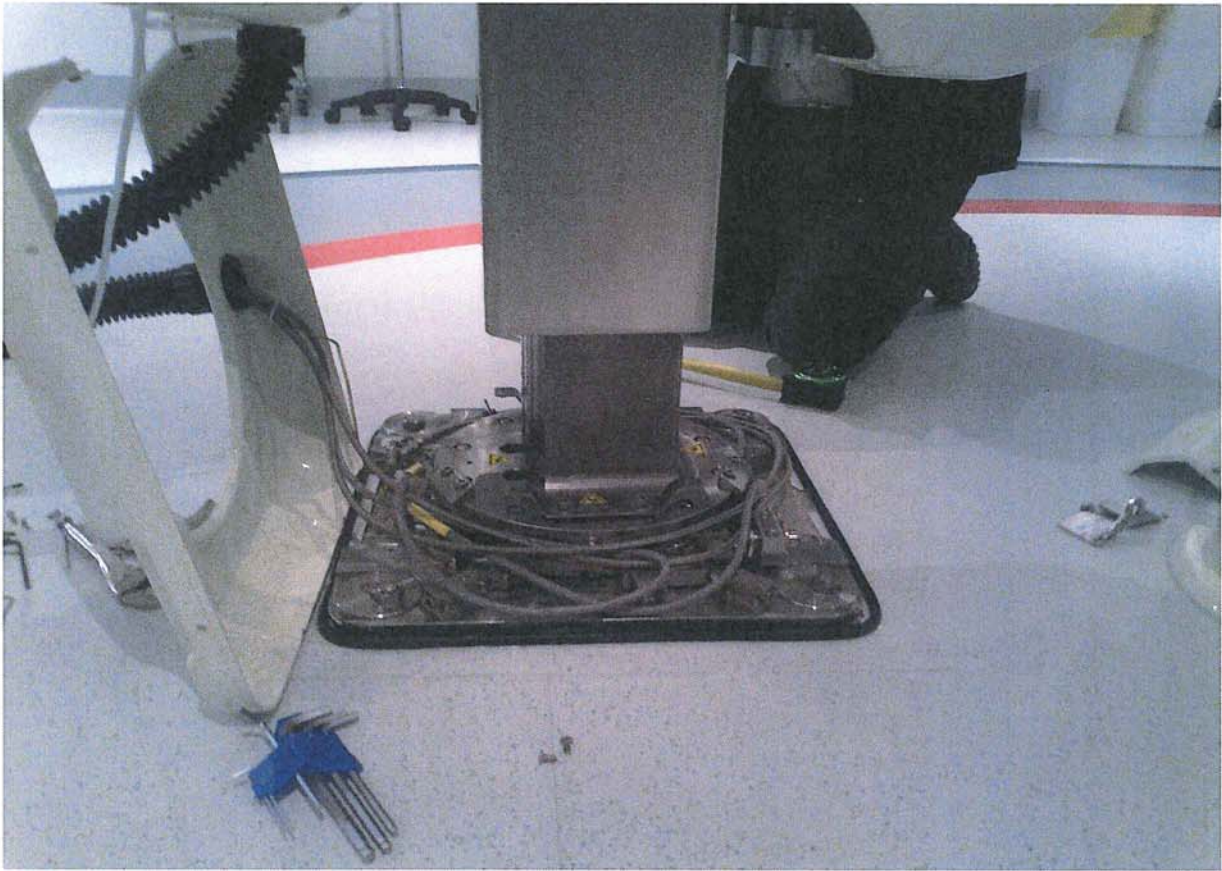
6; Select the correct washer for each of the four studs; align the washers with the etched markings on the bed base, to align the washer to the markings, you will need to move the bed around. Fit anti vibration washer and hand tighten nuts, then tighten nuts diagonally, applying pressure evenly, do not tighten one all the way.



**Note, if the nuts are difficult to screw on, stop and check the threads, there may be a bur to remove with the file, do not force the nut on the stud. All metal burs/fillings must be removed using a vacuum cleaner or magnet.**



7; Run the black control cables & hose through the base cover hole, use the plastic nut to lock the hose in place.



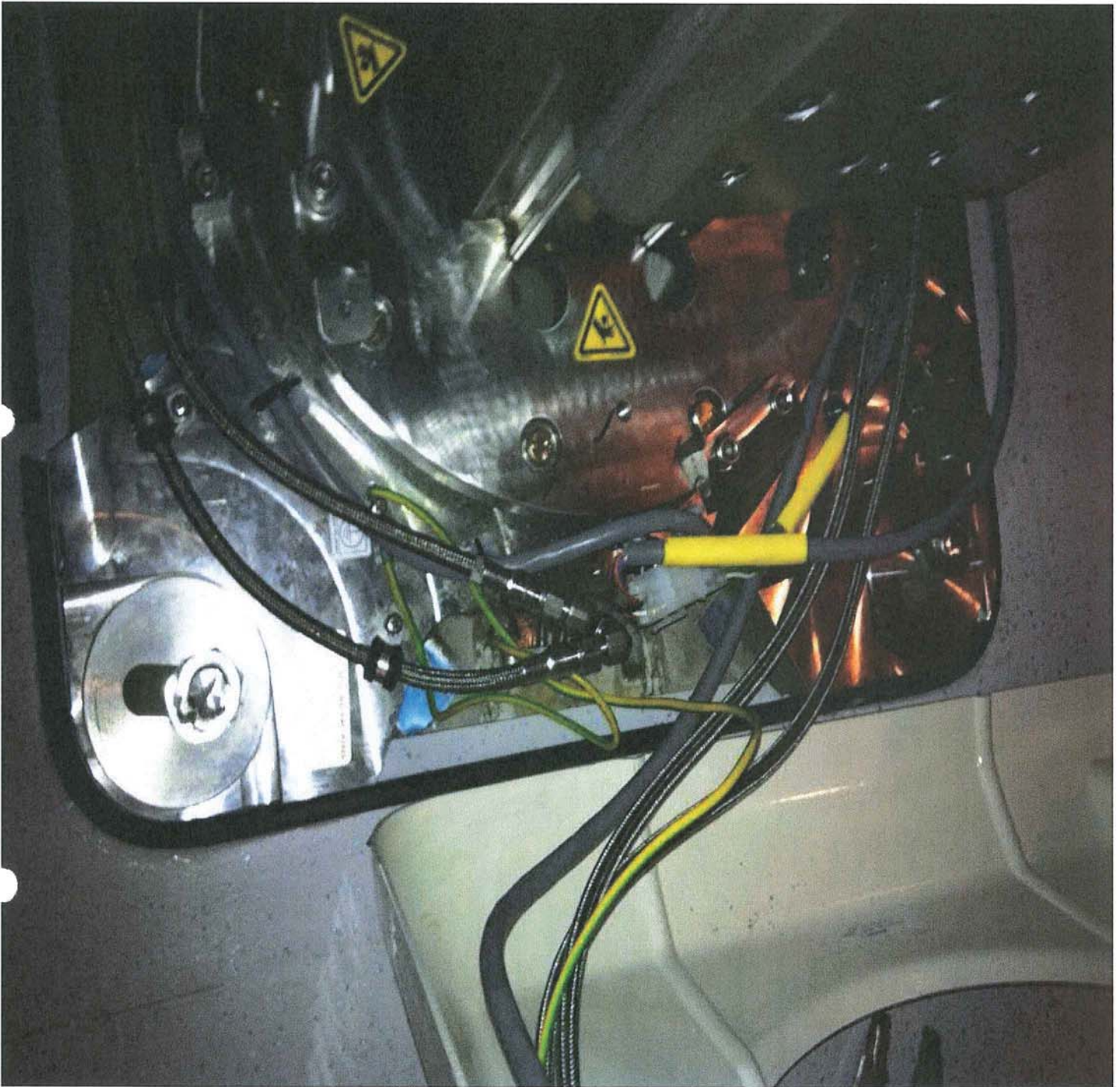


8; Remove the two **red** locking brackets; keep the brackets, Allan bolts & washers in a bag. **Temporarily attach locking pedal make sure base is in Locked position**





9; Connect the control wire, quick coupler, connect the earth wire to the base of the bed.



**Check the direction of the hoses and cables, before attaching!!**



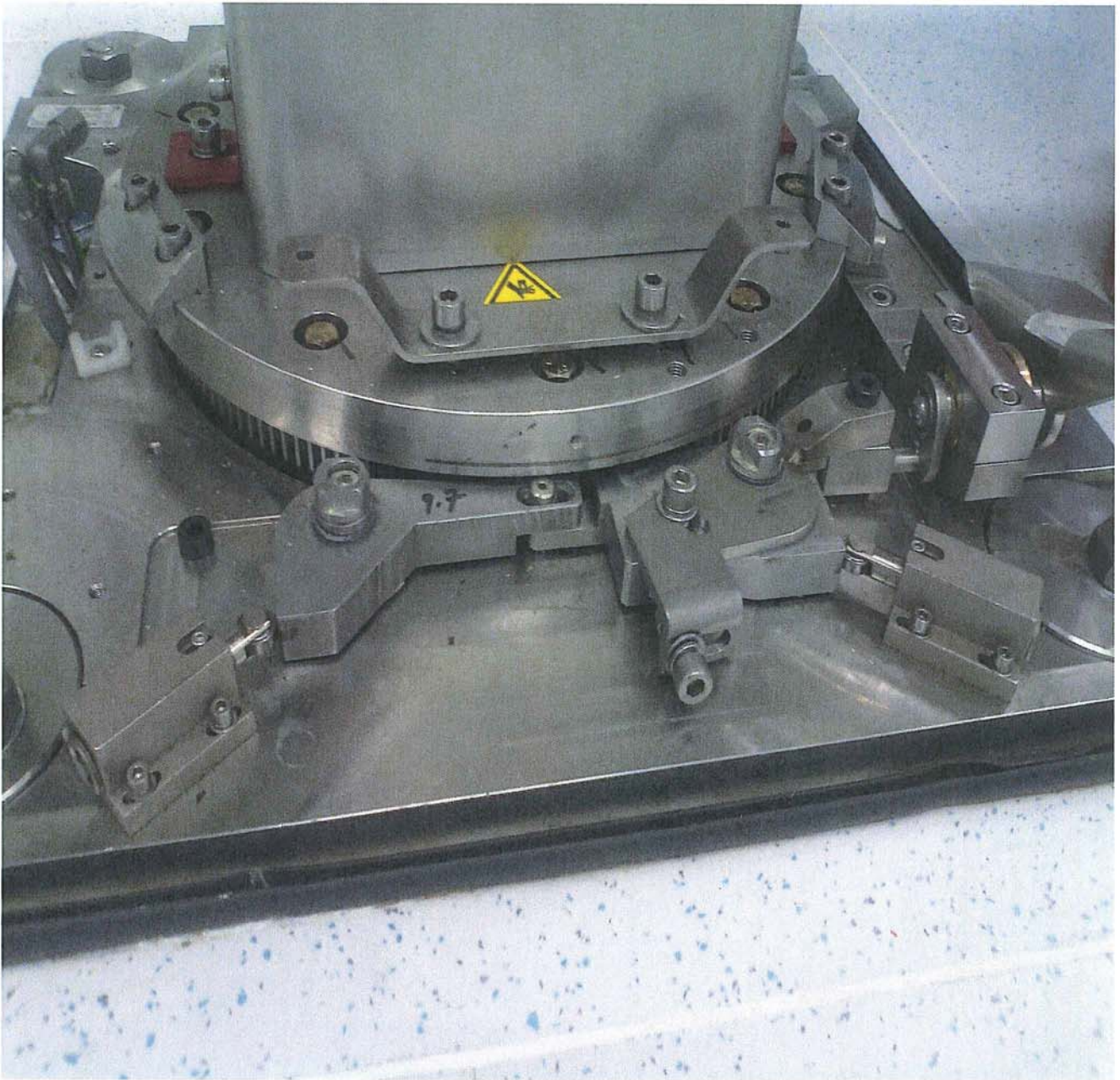
10; Connect the hydraulic hose, correct hoses are connected.  
(Make sure the caps and nuts are kept in a bag)



11; Fit hose clamps and cable ties to hold hydraulic & electrical cables in place.



12; Check that foot operated locking clamp is operating correctly, remove to fit base cover.





12; Confirm power is on, test the bed operation, using hand controller.





13; Fit bed base and pedestal covers, the rubber seal should be fitted to the base, before fitting covers. Retro fit end cover before locking down base panels (the rubber grommets are a pain!)

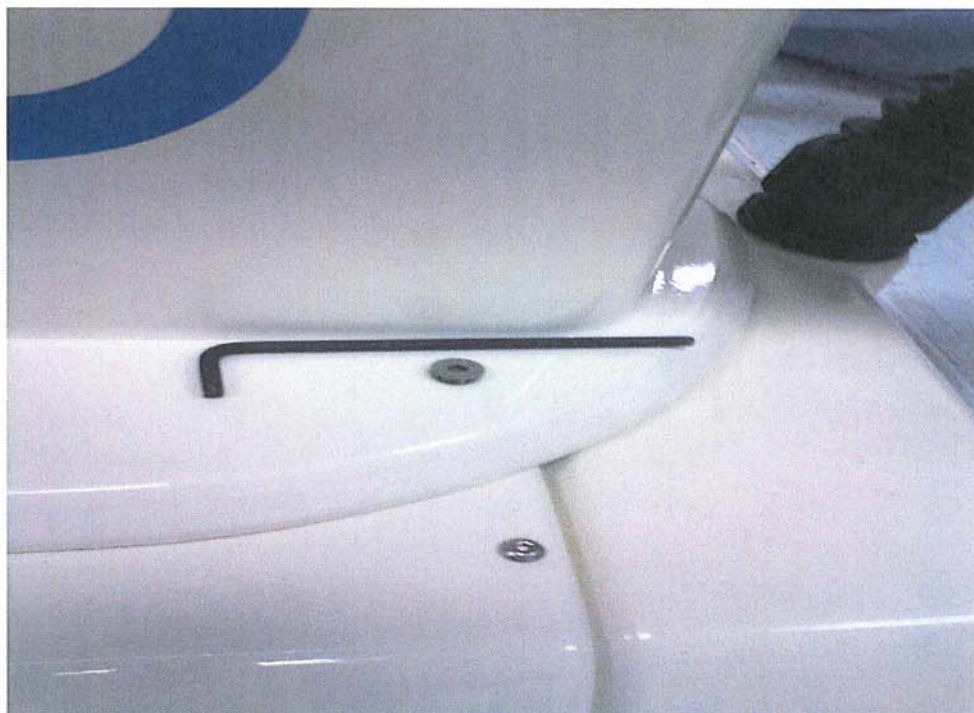








**All the cover screws & self tappers should only be finger tightened before final locking down.**



**Remove the trolley, tool kit and cover panel from the suite, keep all items together, have a check list to ensure nothing has been left behind. Clean up and remove all dust/dirt.**



**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:55 PM  
**To:** McClymont, Geoff  
**Subject:** IMRI FOI - FW: The Neuro Theatre Table

---

**From:** Geoghegan, Sean  
**Sent:** Wednesday, 10 August 2011 5:12 PM  
**To:** Kirchner, Horst  
**Subject:** RE: The Neuro Theatre Table

Thanks Horst,

All saved to a local file.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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---

**From:** Kirchner, Horst  
**Sent:** Wednesday, 10 August 2011 10:30 AM  
**To:** Geoghegan, Sean  
**Subject:** RE: The Neuro Theatre Table

Sean, for your records

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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---

**From:** Geoghegan, Sean  
**Sent:** Tuesday, 9 August 2011 4:03 PM  
**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron; Sommariva, Maurice  
**Cc:** Van Lith, Martin; Thorburn, Phillip; Swain, Rob  
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**From:** Kirchner, Horst

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(I have an engagement most Tuesday evenings)

Unless the theatre is free around 3pm today. (Rhona will let me know)

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*62050363*

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**To:** Kirchner, Horst; JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Scott, Adrian; Robertson, Cameron

**Subject:** FW: The Neuro Theatre Table

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Sean Geoghegan, PhD  
 Chief Medical Physicist ACT Health ACT Australia  
 p: +61 2 6244 2256 f: +61 2 6244 2276 m: +  
 Care ----- Excellence ----- Collaboration ----- Integrity

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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

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Cheers,

Sean

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Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Baker, Jennie  
**Sent:** Monday, 8 August 2011 9:44 AM  
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Jennie

**Jennie Baker**  
Director Business Support  
ACT Health

Phone 02 6244 3045  
Mobile [REDACTED]

[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)

**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:54 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: The Neuro Theatre Table  
**Attachments:** IMRIS REMOVAL OF BED 080711.doc; Material list for Imris Table.docx; Procedure for removing the IMRIS OR Table at Canberra Hospital.pdf; Tool Kit for IMRIS removal.doc

---

**From:** Geoghegan, Sean  
**Sent:** Wednesday, 10 August 2011 5:13 PM  
**To:** Amponin, Gretchen  
**Subject:** FW: The Neuro Theatre Table

Hi Gretchen,

Would you please print these and add to our iMRI file. I've saved them to our NeuroMRI client folder on Q: drive.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: 0409 244 982 | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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*Bldg. 6, L3, TCH*

*62050363*

*mob.0418 864 069*

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Sean Geoghegan, PhD  
 Chief Medical Physicist ACT Health ACT Australia  
 p: +61 2 6244 2256 f: +61 2 6244 2276 m: +61 409 244 982  
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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 21:42  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst; JasonSmith, Rhona; Thorburn, Phillip; Robertson, Cameron  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

sorry to take so long to get back to you.

I believe that it is safe to return the table to use on condition that the SOPs shown to us this morning by Rhona are followed by the Neurosuite staff. These SOPs cover testing that the room is clear of mobile magnetisable objects (covered in their End Of Day Check SOP) and determining that the image quality is clinically sufficient. I caught up with Cameron Robertson after our meeting this morning and he confirmed that they conduct image quality tests on the MRI before use.

The single highest likelihood risk is the risk that the hydraulics will fail. This will eventually happen with work hardening and fatigue of the steel hydraulic connecting tubes at the base of the table stand that protrude from the floor. We probably have many cycles of detachment and reattachment before failure occurs. I believe that a practical alternative to repeatedly detaching and reattaching the hydraulics with the current configuration can be devised in the short to medium term - this will be addressed as part of our risk assessment being developed between Martin Van Lith, Rob Swain, Phil Thorburn and myself.

Tomorrow, the MRI neuro table will need to be reinstalled for a case from 8:00 on Wednesday morning. We'll get the theatre after the last case of the day at approximately 18:00 on Tuesday. We'll need to arrange staff to install the table, and check the installation. I'll liaise with James, Horst and Rhona to make it happen.

I have a full day of meetings tomorrow, but will keep an eye on my e-mails and make sure that we have all arranged before 18:00 tomorrow.

Cheers,

Sean

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 Chief Medical Physicist ACT Health ACT Australia  
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**From:** Geoghegan, Sean  
**Sent:** Monday, 8 August 2011 09:46  
**To:** Baker, Jennie; Thorburn, Phillip  
**Subject:** RE: The Neuro Theatre Table

Hi Jennie,

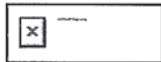
I'll provide you with an opinion after our meeting with Rhona this morning at 10:00.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems  
 Phone: 6244 2256 | Mobile: 0409 244 982 | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Baker, Jennie  
**Sent:** Monday, 8 August 2011 9:44 AM  
**To:** Geoghegan, Sean; Thorburn, Phillip  
**Subject:** The Neuro Theatre Table

Hi Gentlemen,

Adrian has informed me that we will receive a request to reinstall the MRI table for a case on Wednesday.

In your professional opinions do you consider it safe for use as a MRI/Neuro table after installation by the Facilities/BME team?

Jennie

**Jennie Baker**  
 Director Business Support  
 ACT Health

Phone 02 6244 3045  
 Mobile 0408 060 349

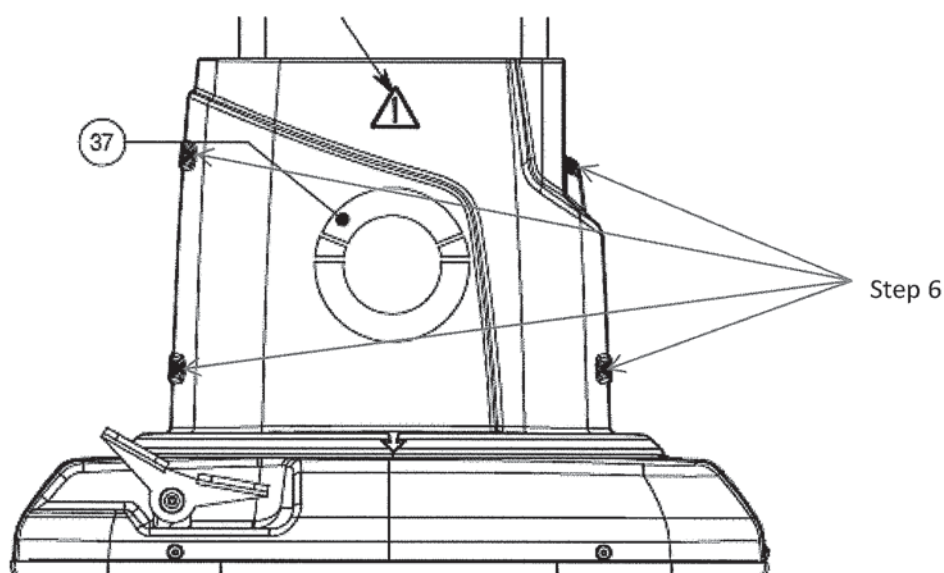
[jennie.baker@act.gov.au](mailto:jennie.baker@act.gov.au)

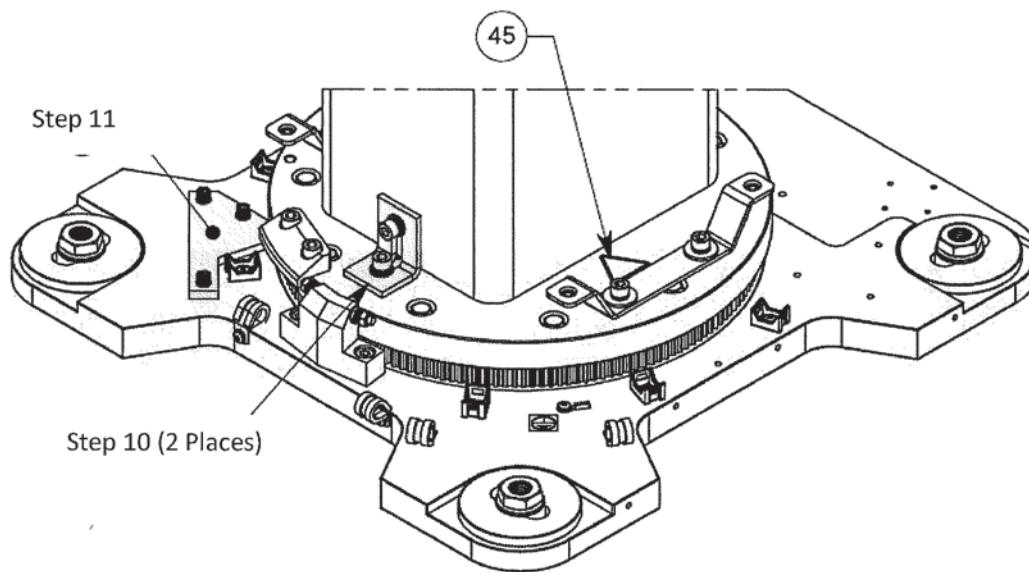
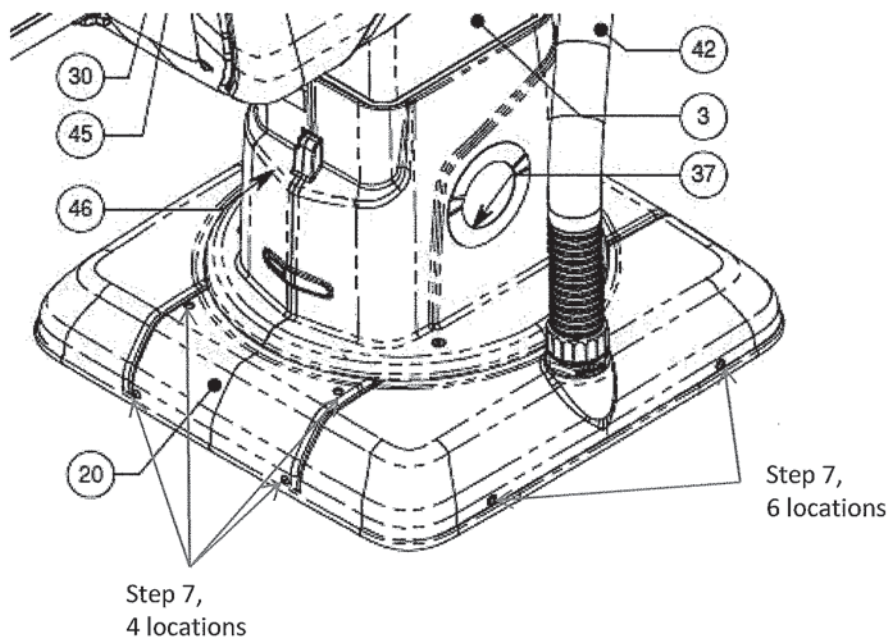


### Procedure for removing the IMRIS OR Table at Canberra Hospital.

Below are the instructions for removal of the table from the floor in the Operating Room.

1. Turn on the table at the pendant and lower the table to its lowest position. Ensure that the table is level with the floor.
2. Remove the radiolucent back section from the table so that you are left with only the stainless body of the table (refer to Operator's Manual for instructions on removal of the back section).
3. Turn off power to the table at the pendant, and turn off the circuit breaker to the table control panel.
4. Release the rotary lock at the table base so that the table can rotate freely.
5. Remove the rotary lock pedal (1 x socket head cap screw).
6. Remove the 4 screws securing the upper pedestal cover.
7. Remove the screws from the lower pedestal cover
8. Disconnect the control cable (grey), and ground cable (green) at the base of the table.
9. Disconnect the hydraulic lines at the base of the table and install the caps provided to prevent fluid loss and ingress of dust or dirt.
10. Install the right angle shipping brackets on two sides of the pedestal
11. Align the table with the base plate and then install the rotary lock.
12. The 4 nuts securing the table to the floor may now be released and the table lifted from the floor. The table may be lifted by the side rails.
13. Lock the magnet door controller and remove the key to prevent someone from accidentally bringing the magnet into the room with the wrong OR table installed.





REFERENCE VIEW  
SHIPPING STAGE

# Material list for Imris Table

## Cover plate, stainless steel;

- 4 caps nuts
- 6 stainless washers
- 8 rubber washers





## Pedestal covers, (plastic/ fibre glass)

2 side piece,

- 4 stainless steel cap screw (screw both section together)
- 4 stainless countersunk screws (screw to base cover)

1 base piece

- 4 stainless steel cap screws & 4 flat washers (screw to pedestal base)

1 small base centre piece

- 4 rubber grommets, 4 cap screw & washers



## Table fixing items, cable & hose clamps

- 1 Table locking lever, 1 cap screw & washer
- 2 Hydraulic hose caps
- 2 Hydraulic hose plugs
- 1 screw for earth lead
- 4 screw for hose clamps
- 4 plastic cable ties for power cord.



- 2 Red angle brackets, (locking clamp when table is lifted, supplied by IMRIS)
- 4 cap screw, 4 spring washers, 4 flat washers



## Main holding down nuts

- 4 nuts
- 4 anti vibration washes
- 4 locating discs, with slotted holes, each is marked with position on base



| Item               | Description                                   | units | bagged    |
|--------------------|---|-------|-----------|
| Base cover         | Large plastic base cover                      | 1     |           |
| Base cover         | Small end cover                               | 1     |           |
| Side covers        | Side covers for pedestal                      | 2     |           |
| Cover screws       | Stainless 4 mm, 30mm                          | 4     |           |
| washers            | Flat washers for above                        | 4     | 1 missing |
| Cap screws         | 3mm screw for side covers                     | 4     |           |
| Countersunk screws | 6mm screw to fit side cover to base cover     | 4     |           |
| End cap screws     | Stainless 4 mm 23 mm                          | 4     |           |
| Rubber grommets    | 4 units for end cap                           | 4     | 1 missing |
| Screws             | 4.5 mm Phillips head, for Earth lead & cables | 1     |           |
| End caps           | Stainless end caps for Hydraulic hose         | 2     |           |
| Hose plugs         | Stainless hose plugs for Hydraulic hose       | 2     |           |
| Holding Brackets   | Red angle pieces                              | 2     |           |
| Cap screws         | 10mm to lock angle pieces                     | 4     |           |
| Washers            | Spring washers for above                      | 4     |           |
| Washers            | Flat washers for above                        | 4     |           |
| Locking lever      | Pedestal locking lever, foot operated         | 1     |           |
| Cap screw          | 8mm screw to fit lock lever                   | 1     |           |
| Washers            | Flat & spring for above                       | 2     |           |
| Stud Cover tubes   | Plastic tube pieces for stude                 | 8     |           |

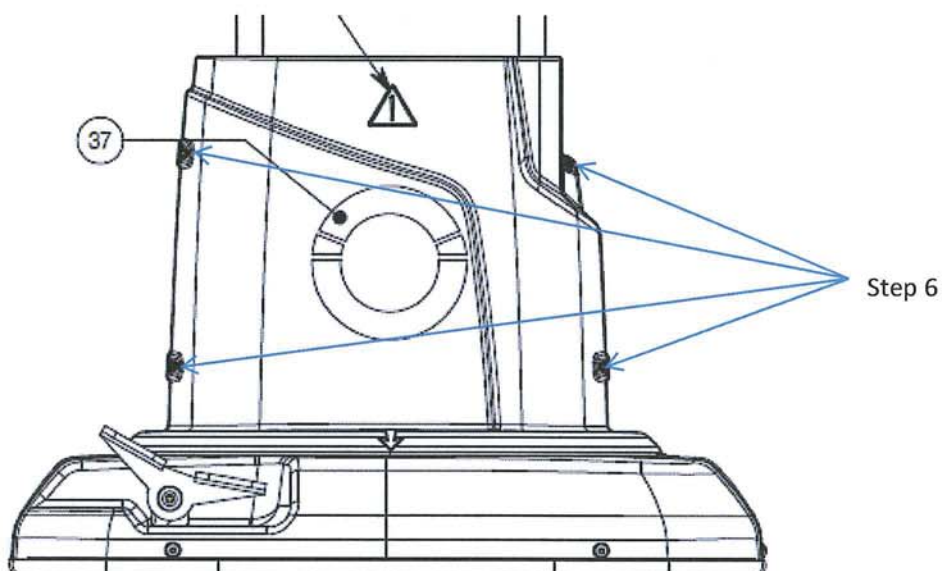
**Spare items, bagged.**

|  |                          |    |  |
|--|--------------------------|----|--|
|  | Stainless screws 4mm     | 6  |  |
|  | Cap screw, stainless 4mm | 3  |  |
|  | Rubber washers           | 12 |  |
|  | Cover Tubes for studs    | 4  |  |
|  | Cap washers              |    |  |

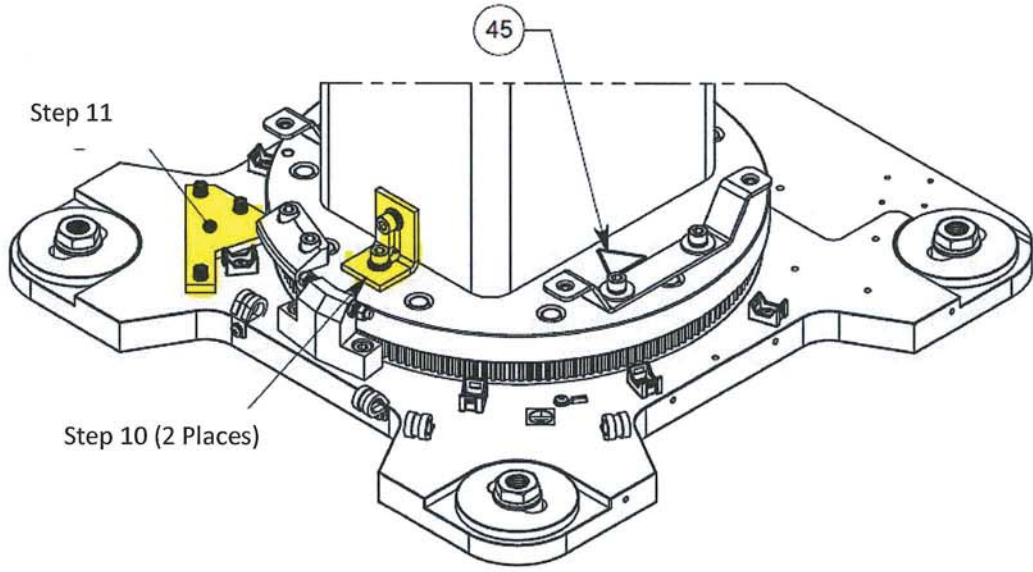
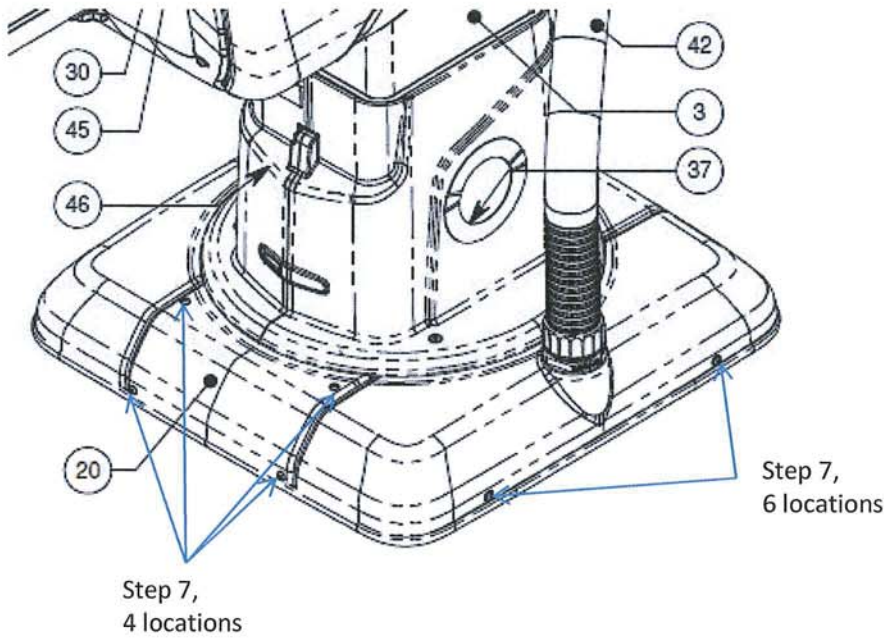
### Procedure for removing the IMRIS OR Table at Canberra Hospital.

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6. Remove the 4 screws securing the upper pedestal cover.
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11. Align the table with the base plate and then install the rotary lock.
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13. Lock the magnet door controller and remove the key to prevent someone from accidentally bringing the magnet into the room with the wrong OR table installed.







REFERENCE VIEW  
SHIPPING STAGE

**Kirchner, Horst**

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**From:** Kirchner, Horst  
**Sent:** Thursday, 11 August 2011 2:40 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** FW: locking

Dawn, for your info.

cheers

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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**From:** Kirchner, Horst  
**Sent:** Thursday, 11 August 2011 2:36 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED] Van Lith, Martin  
**Subject:** locking

[REDACTED]  
 I am concerned about the table locking device, what progress is there on the replacement.  
 The lock is not very secure.

regards

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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---

**From:** Kirchner, Horst  
**Sent:** Friday, 24 June 2011 8:29 AM  
**To:** [REDACTED]  
**Subject:** RE:

[REDACTED] thanks for the update.

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob.* [REDACTED]

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**From:** [REDACTED]

**Sent:** Thursday, 23 June 2011 10:36 PM

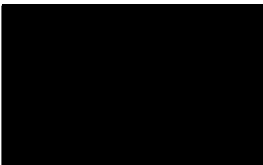
**To:** Kirchner, Horst

**Subject:** RE:

Horst:

We are in the process of releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock. The parts are going into production next week, so I will soon have a date for the delivery of the parts to my group for implementation. The updates will be scheduled with each customer once I have the delivery dates for the parts.

Best Regards,



---

**From:** Kirchner, Horst [<mailto:Horst.Kirchner@act.gov.au>]

**Sent:** June-22-11 9:59 PM

**To:** [REDACTED]

**Subject:**

[REDACTED] we are taking the table of the floor today, I noticed that the locking pin (picture) was quite loose, this does not seem right, as the table moves when locked?.

cheers

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. 0418 864 069*

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This email has been scanned by the IMRIS Email Security System.

This email has been scanned by the IMRIS Email Security System

**McClymont, Geoff**

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**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 5:00 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan  
**Attachments:** Risk\_Plan\_20110811.docx

---

**From:** Geoghegan, Sean  
**Sent:** Thursday, 11 August 2011 5:40 PM  
**To:** Van Lith, Martin; Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Baker, Jennie  
**Subject:** RE: UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hi all,

Please find attached my changes to the document – in blue. Significantly I have changed the likelihood of a mechanical failure of the table to “Almost Certain” without mitigation because of the limited number of cycles that the high pressure hydraulic system can be disconnected and reconnected using the current design. I’ve also added several proposed risk treatments to reduce the likelihood of mechanical failure to “Possible”.

All the risks that I have identified in the Excel spreadsheet that I originally distributed have been capture in the current Risk Plan.

I have left Martin’s comments in red.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Van Lith, Martin  
**Sent:** Thursday, 11 August 2011 12:10 PM  
**To:** Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Baker, Jennie  
**Subject:** UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hello all

Still waiting for your comments on the risk management plan for the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

In the meantime, I have added several more risks identified.

New version of risk management plan is attached and please use the attached version for your comment and feedback.

Your comments please today.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
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Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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**From:** Van Lith, Martin

**Sent:** Tuesday, 9 August 2011 2:16 PM

**To:** Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob

**Cc:** Baker, Jennie

**Subject:** Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hello

On Monday we met to discuss the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

Jur task is to develop a risk management plan and identify any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

You raised many risks and issues before and during the meeting that are in the risk management plan. Attached is a DRAFT Risk Management Plan for your comment.

Please return your comments and updates to me on the attached in colour or track changes by COB Wednesday 10 August 2011.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
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Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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# RISK MANAGEMENT PLAN

**DRAFT**

To be used for developing a risk management plan and identifying any risks that should be prioritised and / or escalated to the risk registers. These plans should be used for all activities, projects and business.

**Title (Project / Activity / Program):** Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH **File No:** .....

**Objective / Background:** Developing a risk management plan and identifying any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

**Prepared by:** Martin Van Lith, Phil Thorburn, Sean Geoghegan, Rhona JasonSmith, Horst Kirchner, James Cotterill, Rob Swain **Date:** 10 August 2011

**Reviewed by:** (to be reviewed by Adrian Scott) **Date:** .....

| Risk No.                       | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Interchange IMRIS Table</b> |   |   |                    |                   |                    |                        |   |                                    |                                   |                            |
| 1                              | <p><b>What:</b><br/>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>There are many mechanical parts, such as screws, at the</li> </ul> | <ul style="list-style-type: none"> <li>A dedicated toolkit and parts list has been made for the interchange.</li> <li>A written procedure containing illustrative photographs has been drafted and tested.</li> <li>Workplace safety analysis has been made and issues addressed</li> <li>IMRIS has been consulted throughout the project.</li> <li>Cleaning operating procedure developed and tested.</li> </ul> | Major              | Almost Certain    | Extreme            |                        | <ul style="list-style-type: none"> <li>Develop responsibility and training of staff for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Use a checklist for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Checklist to be used by the installation staff and a separate list by the spotter. Verify lists and sign off at the end of installation.</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>base plate involved in the interchange of the IMRIS operating table.</li> <li>Responsibility and training of staff for the removal and re-installation not clear.</li> <li>The two hydraulic lines and connectors in the floor are thin walled solid metal tubing AND are flexed each time the table is moved. They are held in a flexed position under the cover plate. The stainless steel tubing will caseharden over time in the flexed (stressed) position and is almost certain to crack. The hydraulic lines are also more vulnerable to damage if the table is moved on a regular basis.</li> <li>Every time the table is moved a small amount of oil leaks out and the possibility can arise where air bubbles may become trapped within the lines. The trapped air can then travel throughout the hydraulic circuit.</li> <li>Electrical wire connections need to be applied correctly.</li> <li>Potential for dirt and metal filings to remain in the operating theatre after the interchange.</li> </ul> | <ul style="list-style-type: none"> <li>A purpose built lifting device has been procured to lift, move and support the table during storage when not in use.</li> </ul> |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>Use one independent person as a spotter during removal and re-installation.</li> <li>Independent check each time of the re-installation of the IMRIS ORT100 Operating Table, e.g. mechanical, electrical, alignment, functions of the theatre table, verification of two checklists.</li> <li>Review the mechanical loading capability of the side rails of the IMRIS ORT 100 Operating Table to support its own weight indefinitely and provide a supporting base to the table when in storage if required.</li> <li>Re-engineer the base of the table to allow reliable reconnection of the hydraulic system and increased durability of the connecting tubes.</li> <li>Re-engineer the covers and underlying screw holes to allow reliable refitting of the covers</li> </ul> |                                    |                                   |                            |

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| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>The concrete supporting the base of the table is cracked by the repeated application and removal of loading stress making the base unstable.</li> <li>The screw holes are not aligned with the holes on the cover plates leading to the screw holes needing to be tapped or the cover plates modified (this has a current frequency of about 1 every 3 to 4 reinstallations).</li> <li>The side rails, used to support the table on the table lift when the table is not in use and in storage, fail due to the continual load being placed on the rails.</li> <li>The time pressure to complete the re-installation of the table leading to errors in reassembly of components of the table.</li> <li>The hydraulic system is at very high pressure and the connector fittings are not designed for a large number disconnections and reconections to be made and is almost certain to fail after a finite number of installations.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect movement</li> </ul> |  |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>without the generation of fillings.</li> <li>Schedule the removal and reinstallation of the table allowing at least two hours for the process prior to any cleaning or preparation of the theatre for a clinical case.</li> </ul> |                                    |                                   |                            |

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| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <ul style="list-style-type: none"> <li>in the operating table.</li> <li>Production of metallic filings and the inadvertent deposition of other mobile magnetisable objects which interfere with the MRI magnetic field or act as projectiles when the magnet is moved into the operating theatre.</li> <li>Damage to the table.</li> <li>Injury to a bystander (staff or patient).</li> <li>If the hydraulic lines did fail and there is a sudden loss of hydraulic pressure the effect 'could' be unwanted movement of the table bed and that 'could' create a life threatening situation.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Permanent loss of function for the patient unrelated to the underlying illness.</li> <li>Repairs to the hydraulic lines would be an expensive and lengthy process.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> | Not adequately addressed   | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>IMRIS re-install and certify the ORT100 operating</li> </ul> | Major                              | Possible                          | High                       |
|          | <b>What:</b><br>All liability for using the MRI  |  |                    |                   |                    |                        |   |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments                 | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|---------------------------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p>equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directory.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table is part of the MRI machine as an integrated and calibrated system in the Neurosuite.</li> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>Health Directorate modifying the IMRIS operating table.</li> <li>The purpose of the IMRIS operating table has been changed from fixed equipment to interchangeable.</li> <li>The local IMRIS representative does <i>not</i> support the interchange of the IMRIS operating table and warns against such action.</li> <li>Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a</li> </ul> |  |                    |                   |                    |                        | table may reduce this liability |                                    |                                   |                            |

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| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 3        | <p>range of risk and liabilities</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Legal liability</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> <p><b>What:</b><br/>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Supplier knows that Health Directorate is interchanging the IMRIS Operating Table and advised against it.</li> <li>• Health Directorate have chosen to use the IMRIS Operating Table outside its design parameter.</li> <li>• Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Legal liability</li> </ul> | <ul style="list-style-type: none"> <li>▪</li> </ul>              | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>▪ Seek legal opinion.</li> </ul> | Major                              | Possible                          | High                       |



|   |  |  |
|---|--|--|
| Risk Level after Treatment  |  | Medium   |
| Likelihood Rating after Treatment                                       |  | Possible   |
| Consequence Rating after Treatment                                      |  | Moderate   |
| Risk Treatments   |  |  |
| Acceptability Yes / No  |  |  |
| Current Risk Level  |  | Medium   |
| Likelihood Rating   |  | Possible   |
| Consequence Rating  |  | Moderate   |
| <b>Current Controls</b><br>What do you already do to mitigate the risk? |  | <ul style="list-style-type: none"> <li>• Written operating procedure</li> <li>• Two people installing and one person observing.</li> <li>• Final check and signoff by an independent person following checking the reinstallation.</li> <li>• Written procedures for cleaning</li> <li>• Magnet roller check for metals</li> </ul>   |
| <b>Risk Description</b><br>What can happen and how                      | <ul style="list-style-type: none"> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> <li>• Reputation loss</li> </ul> | <p><b>What:</b><br/>Interchanging the IMRIS operating table causes premature "wear and tear", as well as increases the chance for error.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Written procedure for interchanging the IMRIS operating table not being followed.</li> <li>• Moving the operating table on a regular basis increases wear and tear on the connecting parts.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Extra costs</li> <li>• Interference with theatre booking schedule</li> </ul> |
| Risk No.  | 4  |  |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 5        | <p><b>What:</b><br/>Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Metal cover plate is a trip hazard to staff and mobile equipment in the theatre.</li> <li>• The 'hump' in the metal cover plate presents a hazard if the operating table is moved with a patient.</li> <li>• Busy work environment</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Damage to staff or patients.</li> <li>• Costs</li> </ul> | <ul style="list-style-type: none"> <li>• Workplace safety assessment has been conducted with staff from Workplace Safety and with operating theatre staff.</li> <li>• An operating theatre table to be located over the metal cover plate during use of theatre.</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Ensure that the metal cover plate has an operating theatre table or other large equipment located over it at all times and does not present a trip hazard.</li> </ul> | Major                              | Unlikely                          | High                       |
| 6        | <p><b>What:</b><br/>Present lighting pendants will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• The theatre lights are</li> </ul>  |   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Modifying operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding exiting theatre light.</li> </ul>                             | Major                              | Rare                              | Medium                     |

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| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments                                    | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 7        | <p>considered not as effective when used anywhere else that where the IMRIS Operating Table is located.</p> <ul style="list-style-type: none"> <li>The Jackson Spinal operating theatre table is longer than a normal operating table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Inadequate lighting of the surgical site.</li> <li>Injury to patient</li> <li>Modification of the operating theatre light required for the MRI Neurosuite.</li> <li>Extra costs</li> </ul> <p><b>What:</b></p> <p><b>Due to:</b></p> <p><b>Resulting in:</b></p> | <ul style="list-style-type: none"> <li></li> </ul>               |                    |                   |                    |                           | <ul style="list-style-type: none"> <li></li> </ul> |                                    |                                   |                            |

| Risk No.                             | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 1                                    | <p><b>What:</b><br/>The MRI Neurosuite not being fully utilised for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The full MRI Neurosuite being presently utilised for approx. 12 cases per year.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table but does not have an interchangeable table top.</li> <li>Surgical staff consider that the IMRIS Operating Table is not wide enough (606.5 mm) for general surgery and limited in its use, such as in spinal surgery.</li> <li>The IMRIS ORT 100 Operating Table with the back section</li> </ul> | <ul style="list-style-type: none"> <li>IMRIS claim that the ORT100 operating table was designed to cater for the vast majority of surgical procedures, however admit that certain specialised procedures, such as spinal surgery, are best performed on an alternate table.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table with a wide range of movements and functionality; but essentially it's a standard operating table that is MR compatible.</li> <li>The back section of the ORT100 table is radiolucent and therefore X-ray compatible.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Rotate the IMRIS ORT 100 Operating Table into the least obstructive position, remove the backrest and cover/protect the table top from liquid ingress and damage.</li> <li>Do not use the Jackson Spinal operating theatre table in this operating theatre.</li> <li>Restrict the use of this operating theatre to general surgical, neurosurgical and other procedures that can be performed on the IMRIS ORT 100 Operating Table.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |
| <b>Leave IMRIS Table in Position</b> |   |   |                    |                   |                    |                        |   |                                    |                                   |                            |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p>removed and the body rotated 180 degrees not allowing enough room for the extra long Jackson Spinal operating table.</p> <ul style="list-style-type: none"> <li>Surgical staff not satisfied with using the remaining part of the IMRIS Operating Table top for holding instruments and consumables during surgery.</li> <li>This operating theatre is considered by surgical staff as a neurosuite and not for other surgical procedures that the IMRIS Operating Table would facilitate.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Less surgical treatments</li> <li>Loss of income</li> <li>Not meeting surgical KPIs</li> <li>Loss of reputation</li> </ul> | <ul style="list-style-type: none"> <li>The ORT100 table has a removable back section and the body rotates 180 degrees, which is useful if an alternate operating table is used alongside.</li> <li>There is an optional table top for use with neonates.</li> <li>The MRI Neurosuite is very large, there appears to be adequate room for an alternative normal sized operating table to be used alongside the ORT100 table.</li> <li>IMRIS reported that other hospitals approach the problem by leaving the IMRIS operating table fixed in situ and simply wheel in an alternate table and operate it along-side the IMRIS table.</li> </ul> |                    |                   |                    |                        |                 |                                    |                                   |                            |
| 2        | <p><b>What:</b></p> <p><b>Due to:</b></p> <p><b>Resulting in:</b></p>  |  |                    |                   |                    |                        |                 |                                    |                                   |                            |

| Risk No.                         | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------------------------------|---|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Other Incidental Findings</b> |   |  |                    |                   |                    |                        |   |                                    |                                   |                            |
| 1                                | <p><b>What:</b><br/>Permanent loss of function for the patient unrelated to the underlying illness.</p> <p><b>Due to:</b><br/>The IMRIS ORT100 Operating Table has a defective locking pin mechanism on the swivel of the base that allows limited free movement of the table top even when locked into position.</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unwanted / incorrect movement in the operating table.</li> <li>• Incorrect diagnosis</li> <li>• Error in surgery of the patient.</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> | <ul style="list-style-type: none"> <li>• Moving the operating table top until it is fixed in position after the locking mechanism is applied.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>• Supplier / manufacturer is "releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock".</li> <li>• Supplier / manufacturer to fit new entire locking mechanism.</li> <li>• Supplier / manufacturer to advise Therapeutic goods Administration (TGA) of recall / product correction.</li> </ul> | Major                              | Unlikely                          | High                       |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <p><b>What:</b><br/>MRI Neurosuite equipment not available for surgery.</p> <p><b>Due to:</b><br/>Unclear responsibility for the maintenance and upkeep of the MRI Neurosuite, including the IMRIS ORT100 Operating Table</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect operation in the MRI Neurosuite equipment.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> |   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Clear responsibility and appropriate resourcing for the maintenance and upkeep of the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> </ul>   | Moderate                           | Unlikely                          | Medium                     |
| 3        | <p><b>What:</b><br/>Backlog in surgical operations</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Shortage of operating theatres at TCH.</li> <li>Incompatible operating theatres to the requirements of the</li> </ul>   | <ul style="list-style-type: none"> <li>The two Jackson Spinal operating tables are presently used in the other operating theatres.</li> <li>Daily operating theatre scheduling with little or no spare capacity.</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Upgrade the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed. Estimated to take 16 working days shutdown for</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 4        | <p>surgeons / theatre staff.</p> <ul style="list-style-type: none"> <li>Limited use of operating theatres due to old theatre pendants, theatre lights and communication cables.</li> <li>The MRI Neurosuite is required to be left "Ready To Scan" at the end of each day.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Backlog in surgery cases.</li> <li>No spare operating theatre for shutdown of other theatres to allow replacing the theatre pendants, lights and cabling work; they require updating and making safer.</li> </ul> <p><b>What:</b><br/>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Ferrous objects attracted to the</li> </ul> |  | Moderate           | Possible          | Medium             |                           | <p>each two operating theatres to do the updating work. It would require 4 (set of 2 theatres) x 16 = 64 working days to complete this previously planned work.</p> <ul style="list-style-type: none"> <li>Negotiate agreement with other surgical service providers to facilitate surgery during the remediation work, e.g. Royal Darwin Hospital used portable operating theatres installed on-site from the Defence Department.</li> <li>Re-evaluate interchanging the IMRIS Operating Table after the operating theatre pendants have been replaced in all the other theatres.</li> </ul> <p>Conduct a metal sweep with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</p> | Moderate                           | Unlikely                          | Medium                     |





| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p>magnet.</p> <ul style="list-style-type: none"> <li>Leaving small metal items or fragments after surgery in the MRI Neurosuite that will be attracted to the magnet when it starts to function, such as pins, screws, metal thread and fragments from implants.</li> <li>Likelihood of occurrence increase if this theatre is used for some other surgical procedures, e.g. implants, orthopaedic.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unclear images.</li> <li>Injury to staff</li> </ul> |  |                    |                   |                    |                           |                 |                                    |                                   |                            |

**McClymont, Geoff**

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**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 5:00 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

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**From:** Baker, Jennie  
**Sent:** Friday, 12 August 2011 10:17 AM  
**To:** Geoghegan, Sean; Van Lith, Martin; Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Scott, Adrian  
**Subject:** RE: UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hi Sean,

Many thanks for this and to you, Martin & Phil for your time and input. I support this document.

Regards

Jennie

---

**From:** Geoghegan, Sean  
**Sent:** Thursday, 11 August 2011 5:40 PM  
**To:** Van Lith, Martin; Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Baker, Jennie  
**Subject:** RE: UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hi all,

Please find attached my changes to the document – in blue. Significantly I have changed the likelihood of a mechanical failure of the table to “Almost Certain” without mitigation because of the limited number of cycles that the high pressure hydraulic system can be disconnected and reconnected using the current design. I’ve also added several proposed risk treatments to reduce the likelihood of mechanical failure to “Possible”.

All the risks that I have identified in the Excel spreadsheet that I originally distributed have been capture in the current Risk Plan.

I have left Martin’s comments in red.

Cheers,

Sean  
**Sean Geoghegan**  
Chief Medical Physicist Medical Physics and Medical Technology Systems  
Phone: 6244 2256 | Mobile: [REDACTED] | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Van Lith, Martin  
**Sent:** Thursday, 11 August 2011 12:10 PM  
**To:** Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob

**Cc:** Baker, Jennie  
**Subject:** UPDATE - Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hello all

Still waiting for your comments on the risk management plan for the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

In the meantime, I have added several more risks identified.

New version of risk management plan is attached and please use the attached version for your comment and feedback.

Your comments please today.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
***Business and Infrastructure – committed to timely, responsive and client-focused services***  
Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
***Care Excellence Collaboration Integrity***

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**From:** Van Lith, Martin  
**Sent:** Tuesday, 9 August 2011 2:16 PM  
**To:** Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Cc:** Baker, Jennie  
**Subject:** Interchange of IMRIS Operating Room Table in the MRI Neurosuite at TCH - Risk management plan

Hello

On Monday we met to discuss the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

Our task is to develop a risk management plan and identify any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

You raised many risks and issues before and during the meeting that are in the risk management plan. Attached is a DRAFT Risk Management Plan for your comment.

Please return your comments and updates to me on the attached in colour or track changes by COB Wednesday 10 August 2011.

Kind regards

**Martin Van Lith**



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Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
***Care Excellence Collaboration Integrity***

**McClymont, Geoff**

---

**From:** Cotterill, James  
**Sent:** Wednesday, 17 August 2011 11:17 AM  
**To:** [REDACTED]  
**Subject:** Manufacturing defect IMRIS MRI table

[REDACTED]  
IMRIS Australia

Hi Jeff,

You may recall we were in contact a few weeks ago regarding the removal of the IMRIS table at the Canberra Hospital.

Now we have another issue... upon installation of the table last week we noticed the table itself was unstable. The problem was found to be related to the manual locking mechanism which allows the table be unlocked and rotated up to 180 degrees.

There appears to be a manufacturing defect in this locking mechanism which allows too much free play..as a consequence the table can move sideways.

As you can imagine this poses a serious risk to patient safety, accordingly we, Biomedical Engineering are advising our staff not to use the table until it has been repaired.

I was made aware that IMRIS was also aware of this issue and is producing a in the field upgrade kit. Could you please let me know when our table could be fitted with the upgrade.

Many thanks

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**McClymont, Geoff**

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**From:** Cotterill, James  
**Sent:** Thursday, 18 August 2011 8:13 AM  
**To:** [REDACTED]  
**Cc:** JasonSmith, Rhona  
**Subject:** FW: Table repair

[REDACTED]

Our Assistant Director of Nursing Perioperative Services is Rhona Jason Smith.  
Her contact details are as follows:

Ph (02) 62443051  
email: [Rhona.JasonSmith@act.gov.au](mailto:Rhona.JasonSmith@act.gov.au)

Many thanks

James Cotterill  
Biomedical Engineering  
The Canberra Hospital

(02) 62443831

-----Original Message-----

**From:** [REDACTED]  
**Sent:** Wednesday, 17 August 2011 10:05 PM  
**To:** Cotterill, James  
**Cc:** [REDACTED]  
**Subject:** Table repair

Hi James

As discussed yesterday could you please forward the contact details for theatre manager so that I can arrange a time to carry out the repairs.

Once I have arrange a time I will let you know so that we can meet up will I am on site.

My direct contact details are

[REDACTED]

Regards  
Michael Thomas

This email has been scanned by the IMRIS Email Security System

**McClymont, Geoff**

---

**From:** Van Lith, Martin  
**Sent:** Thursday, 18 August 2011 11:38 AM  
**To:** Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Geoghegan, Sean; Swain, Rob  
**Cc:** Scott, Adrian; Baker, Jennie  
**Subject:** Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH  
**Attachments:** Review report 180811.docx; Risk\_Plan\_20110818.docx

Hello

I was able to speak with Dr John Fuller, Head of Neurosurgery yesterday and obtain his views on the interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH. His comments are included in the report.

A draft report is attached for your review and updating.

Your changes, updates, corrections **back to me by early morning Friday 19 August 2011.**

Kind regards

**Martin Van Lith**



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**Business & Infrastructure Branch**  
with support from  
**Surgery and Oral Health Division**  
&  
**Quality and Safety Unit**

**Review**

**Interchange of IMRIS Operating Room Table in  
the MRI Neurosuite at TCH**

**Draft - Final Report**

18 August 2011

## Executive Summary

The review set out to develop a risk management plan and identify key risks associated with the frequent interchange (removal and re-installation) of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

The review considered the risks for interchanging the IMRIS Operating Room Table and also for leaving it in position. The reviewing process uncovered other important and closely related risks.

The identified key risks were analysed, current controls identified, assessed and risk treatments proposed to lower the risk levels.

Recommendations were based on the proposed risk treatments for interchanging the IMRIS Operating Room Table and also for leaving it in position.

### 1. Report Owner

The review was initiated and the report is owned by the Business & Infrastructure Branch Executive Director, currently acting in this position is Mr Adrian Scott.

The review team included:

Martin Van Lith - Coordinator, Accreditation & Risk Management, Business & Infrastructure Branch.

Phil Thorburn – Biomedical Engineer, Redevelopment Unit, Service & Capital Planning

Rhona JasonSmith - Assistant Director of Nursing Perioperative Services

Horst Kirchner - Project Manager, Strategic Asset Management & Accommodation

James Cotterill - Biomedical Engineering Technician, Clinical Engineering

Sean Geoghegan - Chief Medical Physicist, Medical Physics and Medical Technology Systems

Rob Swain - Assistant Director, Workplace Safety, Quality & Safety Unit

### 2. Review Objectives and Scope

The objectives of the review team were to:

- Establish the facts with the interchange of the IMRIS Operating Room Table using Risk Analysis
- Provide a report of the review findings and formulate recommendations
- Look for system gaps and opportunities for improvement

The scope of the review included the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

### 3. Review Process

The review process consisted of:

- A documentation review including related Emails and Product Manuals;
- Site visits and demonstration of the re-installation;
- Interviews with key stakeholders;
- Analysis of findings utilising risk analysis;
- Reporting of the findings and recommendations; and
- A risk analysis to support the report (Attachment A).

A telephone discussion was held with Dr John Fuller, Head of Neurosurgery, on 17 August 2011. He stated that the MRI Neurosuite should be used more often as an operating theatre and not wasted. He also stated that as a surgeon he considered that the IMRIS Operating Table was not suitable for other surgery. His opinion was that the operating theatre should be used and that it required the IMRIS Operating Table be moved to make way for other operating theatre tables.

#### **4. Summary of Key Risks and Recommendations**

The review found that most interviewed stakeholders were concerned over the governance, management and safety associated with the frequent interchange (removal and re-installation) of IMRIS Operating Table in the MRI Neurosuite at TCH.

The Risk Management Plan in Attachment A contains the key risks that fell into the following main categories:

- Clinical
- People
- Property and Services
- Financial
- Business Process and Systems
- Reputation



## Key Risks and Recommendations

| Risks   | Recommendation  |
|---|---|
| <ul style="list-style-type: none"> <li>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</li> <li>All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directory.</li> <li>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</li> <li>Interchanging the IMRIS operating table causes premature 'wear and tear', as well increases the chance for error during each installation.</li> <li>Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</li> </ul> | <p>1.1 Do not interchange the IMRIS ORT100 Operating Table in the MRI Neurosuite.</p> <p>OR</p> <p>1.2 If the IMRIS ORT100 Operating Table is to be interchanged then implement the risk treatments outlined in the Risk Management Plan</p>  |
|   | <b>Recommendation</b>   |
| <p>Permanent loss of function for the patient unrelated to the underlying illness.</p>  | <p>2.1 Supplier / manufacturer to fit a new entire locking mechanism to the IMRIS ORT100 Operating Table.</p> <p>2.2 Health Directorate notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</p>   |
| <b>Risk</b>   | <b>Recommendation</b>   |
| <p>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p>   | <p>3.1 Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</p> <p>3.2 Appropriate training and endorsement by the manufacturer for the maintenance staff &amp; other staff for the IMRIS ORT100 Operating Table.</p> |
| <b>Risk</b>   | <b>Recommendation</b>   |
| <p>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p>  | <p>4.0 Modify operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding existing theatre light.</p>   |
| <b>Risk</b>   | <b>Recommendation</b>   |
| <p>The MRI Neurosuite not being fully utilised for surgery.</p>   | <p>5.1 Utilise the IMRIS ORT 100 Operating Table into the least obstructive position when using other operating theatre tables,</p> <p>AND / OR</p> <p>5.2 Regulate the use of the MRI Neurosuite to surgical procedures that can be performed on the IMRIS ORT 100 Operating Table.</p>  |

| Risk   | Recommendation   |
|--|--|
| Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.                               | 6.0 Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed.  |
| Risk   | Recommendation   |
| Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments | <p>7.1 Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this operating theatre, including the cleaning, technical and clinical staff.</p> <p>7.2 Schedule appropriate surgical cases for this operating theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</p> <p>7.3 Conduct a metal sweep of the operating theatre with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</p> |

## 5. Conclusion

The risk management plan identified key risks associated with the frequent interchange (removal and re-installation) and also for leaving fixed the IMRIS Operating Table in the MRI Neurosuite at TCH. The process also highlighted other important and closely related risks.

The risk management planning process identified three extreme level, six high level and two medium level risks.

Expedient attention is urged to address the following three extreme level risks.

1. It is recommended that the IMRIS ORT100 Operating Table not be interchanged. The review identified an extreme risk associated with interchanging the IMRIS ORT100 Operating Table from the adverse effect on the correct and accurate function of the table, premature 'wear and tear', increased chance for error during installation, increased liability and possibility to increased litigation exposure, as well as staff or patient on an operating table being injured from unexpectantly coming in contact with the metal floor plate.

If the IMRIS ORT100 Operating Table is to be interchanged then it is recommended that the risk treatments outlined in the Risk Management Plan under Risk Nos. 1, 2, 3 4 and 5 be implemented.

2. It is recommended that the supplier/manufacturer of the IMRIS ORT100 Operating Table fits a new entire locking mechanism and that the Therapeutic Goods Administration (TGA) be notified of the problem with the Table. Limited free movement of the table top presents an extreme risk from permanent loss of function for the patient unrelated to the underlying illness.
3. It is also recommended that responsibility and appropriate resources be allocated, including ongoing costs, for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table. Appropriate training is required and endorsement by the manufacturer for the maintenance staff & other staff for the IMRIS ORT100 Operating Table.

Recommendations 4.0, 5.1, 5.2, 6.0, 7.1, 7.2 and 7.3 listed in the Table above also apply and are presented for follow-up and action to lower the other high and medium risks identified during the review.

# RISK MANAGEMENT PLAN

**DRAFT**

To be used for developing a risk management plan and identifying any risks that should be prioritised and / or escalated to the risk registers. These plans should be used for all activities, projects and business.

**Title (Project / Activity / Program):** Interchange of IMRIS Operating Table in the MRI Neurosuite at TCH **File No:** .....

**Objective / Background:** Developing a risk management plan and identifying any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

**Prepared by:** Martin Van Lith, Phil Thorburn, Sean Geoghegan, Rhona JasonSmith, Horst Kirchner, James Cotterill, Rob Swain **Date:** 18 August 2011

**Reviewed by:** Adrian Scott **Date:** .....

| Risk No.                       | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------|---|---|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Interchange IMRIS Table</b> |   |   |                    |                   |                    |                        |   |                                    |                                   |                            |
| 1                              | <p><b>What:</b><br/>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>There are many mechanical parts, such as screws, at the</li> </ul> | <ul style="list-style-type: none"> <li>A dedicated toolkit and parts list has been made for the interchange.</li> <li>A written procedure containing illustrative photographs has been drafted and tested.</li> <li>Workplace safety analysis has been made and issues addressed</li> <li>IMRIS has been consulted throughout the project.</li> <li>Cleaning operating procedure developed</li> </ul> | Major              | Almost certain    | Extreme            |                        | <ul style="list-style-type: none"> <li>Develop responsibility and training of staff for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Use a checklist for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Checklist to be used by the installation staff and a separate list by the spotter. Verify lists and sign off at the end of installation.</li> </ul> | Major                              | Possible                          | High                       |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|---|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>base plate involved in the interchange of the IMRIS operating table.</li> <li>Responsibility and training of staff for the removal and re-installation not clear.</li> <li>The two hydraulic lines and connectors in the floor are thin walled solid metal tubing AND are flexed each time the table is moved. They are held in a flexed position under the cover plate. The stainless steel tubing will caseharden over time in the flexed (stressed) position and is almost certain to crack. The hydraulic lines are also more vulnerable to damage if the table is moved on a regular basis.</li> <li>The hydraulic system is at very high pressure and the connector fittings are not designed for a large number disconnections and reconnections to be made and is almost certain to fail after a finite number of installations.</li> <li>Every time the table is moved a small amount of oil leaks out and the possibility can arise where air bubbles may become trapped within the lines. The trapped air can then travel</li> </ul> | <ul style="list-style-type: none"> <li>and tested.</li> <li>A purpose built lifting device has been procured to lift, move and support the table during storage when not in use.</li> </ul> |                    |                   |                    |                           | <ul style="list-style-type: none"> <li>Use one independent person as a spotter during removal and re-installation.</li> <li>Independent check each time of the re-installation of the IMRIS ORT100 Operating Table, e.g. mechanical, electrical, alignment, functions of the theatre table, verification of two checklists.</li> <li>Review the mechanical loading capability of the side rails of the IMRIS ORT 100 Operating Table to support its own weight indefinitely and provide a supporting base to the table when in storage if required.</li> <li>Re-engineer the base of the table to allow reliable reconnection of the hydraulic system and increased durability of the connecting tubes.</li> <li>Re-engineer the covers and underlying screw holes to allow reliable refitting of the covers without the generation of</li> </ul> |                                    |                                   |                            |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>throughout the hydraulic circuit.</li> <li>Electrical wire connections need to be applied correctly.</li> <li>Potential for dirt and metal filings to remain in the operating theatre after the interchange</li> <li>The concrete supporting the base of the table is cracked by the repeated application and removal of loading stress making the base unstable.</li> <li>The screw holes are not aligned with the holes on the cover plates leading to the screw holes needing to be tapped or the cover plates modified (this has a current frequency of about 1 every 3 to 4 reinstallations).</li> <li>The side rails, used to support the table on the table lift when the table is not in use and in storage, fail due to the continual load being placed on the rails.</li> <li>The time pressure to complete the re-installation of the table leading to errors in reassembly of components of the table.</li> </ul> |  |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>filings. Schedule the removal and reinstallation of the table allowing at least two hours for the process prior to any cleaning or preparation of the theatre for a clinical case.</li> </ul> |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unwanted / incorrect movement in the operating table.</li> <li>• Production of metallic filings and the inadvertent deposition of other mobile magnetisable objects which interfere with the MRI magnetic field or act as projectiles when the magnet is moved into the operating theatre.</li> <li>• Damage to the table.</li> <li>• Injury to a bystander (staff or patient).</li> <li>• If the hydraulic lines did fail and there is a sudden loss of hydraulic pressure the effect 'could' be unwanted movement of the table bed and that 'could' create a life threatening situation.</li> <li>• Incorrect diagnosis</li> <li>• Error in surgery of the patient.</li> <li>• Permanent loss of function for the patient unrelated to the underlying illness.</li> <li>• Repairs to the hydraulic lines would be an expensive and lengthy process.</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> |  |                    |                   |                    |                           |                 |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <p><b>What:</b><br/>All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directory.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table is part of the MRI machine as an integrated and calibrated system in the Neurosuite.</li> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>Health Directorate modifying the IMRIS operating table.</li> <li>The purpose of the IMRIS operating table has been changed from fixed equipment to interchangeable.</li> <li>The local IMRIS representative does <i>not</i> support the interchange of the IMRIS operating table and warns against such action.</li> <li>Removing the IMRIS Operating Table has voided the</li> </ul> | Not adequately addressed   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>IMRIS re-install and certify the ORT100 operating table may reduce this liability</li> </ul> | Major                              | Possible                          | High                       |

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| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 3        | <p>manufacturer's warranty and introduced the possibility for a range of risk and liabilities</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Legal liability</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> <p><b>What:</b><br/>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Supplier knows that Health Directorate is interchanging the IMRIS Operating Table and advised against it.</li> <li>• Health Directorate have chosen to use the IMRIS Operating Table outside its design parameter.</li> <li>• Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> | <ul style="list-style-type: none"> <li>•</li> </ul>              | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Seek legal opinion.</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
| 4        | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Legal liability</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> <li>Reputation loss</li> </ul> <p><b>What:</b><br/>Interchanging the IMRIS operating table causes premature "wear and tear", as well as increases the chance for error.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Written procedure for interchanging the IMRIS operating table not being followed.</li> <li>Moving the operating table on a regular basis increases wear and tear on the connecting parts.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Extra costs</li> <li>Interference with theatre booking schedule</li> </ul> | <ul style="list-style-type: none"> <li>Written operating procedure</li> <li>Two people installing and one person observing.</li> <li>Final check and signoff by an independent person following checking the reinstallation.</li> <li>Written procedures for cleaning</li> <li>Magnet roller check for metals</li> </ul> | Moderate           | Possible          | Medium             |                           |                 | Moderate                           | Possible                          | Medium                     |



| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 5        | <p><b>What:</b><br/>Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Metal cover plate is a trip hazard to staff and mobile equipment in the theatre.</li> <li>• The 'hump' in the metal cover plate presents a hazard if the operating table is moved with a patient.</li> <li>• Busy work environment</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Damage to staff or patients.</li> <li>• Costs</li> </ul> | <ul style="list-style-type: none"> <li>• Workplace safety assessment has been conducted with staff from Workplace Safety and with operating theatre staff.</li> <li>• An operating theatre table to be located over the metal cover plate during use of theatre.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>• Ensure that the metal cover plate has an operating theatre table or other large equipment located over it at all times and does not present a trip hazard.</li> </ul> | Major                              | Unlikely                          | High                       |
| 6        | <p><b>What:</b><br/>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• The configuration and location of the theatre lights does not</li> </ul>   |   | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>• Modifying operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding exiting theatre light.</li> </ul>                             | Major                              | Rare                              | Medium                     |

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| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p>provide as effective lighting of the surgical sites when used outside the allocated area for the fixed IMRIS Operating Table.</p> <ul style="list-style-type: none"> <li>The Jackson Spinal operating theatre table is longer than a normal operating table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Inadequate lighting of the surgical site.</li> <li>Injury to patient</li> <li>Modification of the operating theatre light required for the MRI Neurosuite.</li> <li>Extra costs</li> </ul> |  |                    |                   |                    |                           |                 |                                    |                                   |                            |

SGA

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 7.       | <p><b>What:</b><br/>The MRI Neurosuite not being fully utilised for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The full MRI Neurosuite being presently utilised for approx. 12 cases per year.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table but does not have an interchangeable table top.</li> <li>Surgical staff consider that the IMRIS Operating Table is not wide enough (606.5 mm) for general surgery and limited in its use, such as in spinal surgery.</li> <li>The IMRIS ORT 100 Operating Table with the back section removed and the body rotated 180 degrees not allowing enough room for the extra long Jackson Spinal operating table.</li> <li>Surgical staff not satisfied with using the remaining part of the IMRIS Operating Table top for holding instruments and consumables during surgery.</li> </ul> | <ul style="list-style-type: none"> <li>IMRIS claim that the ORT100 operating table was designed to cater for the vast majority of surgical procedures, however admit that certain specialised procedures, such as spinal surgery, are best performed on an alternate table.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table with a wide range of movements and functionality; but essentially it's a standard operating table that is MIR compatible.</li> <li>The back section of the ORT100 table is radiolucent and therefore X-ray compatible.</li> <li>The ORT100 table has a removable back section and the body rotates 180 degrees, which is useful if an alternate operating table is used alongside.</li> <li>There is an optional table</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Rotate the IMRIS ORT 100 Operating Table into the least obstructive position, remove the backrest and cover/protect the table top from liquid ingress and damage.</li> <li>Do not use the Jackson Spinal operating theatre table in this operating theatre.</li> <li>Regulate the use of this operating theatre to general surgical, neurosurgical and other procedures that can be performed on the IMRIS ORT 100 Operating Table.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>This operating theatre is considered by surgical staff as a neurosuite and not for other surgical procedures that the IMRIS Operating Table would facilitate.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Less surgical treatments</li> <li>Loss of income</li> <li>Not meeting surgical KPIs</li> <li>Loss of reputation</li> </ul> | <ul style="list-style-type: none"> <li>top for use with neonates.</li> <li>The MRI Neurosuite is very large, there appears to be adequate room for an alternative normal sized operating table to be used alongside the ORT100 table.</li> <li>IMRIS reported that other hospitals approach the problem by leaving the IMRIS operating table fixed in situ and simply wheel in an alternate table and operate it along-side the IMRIS table.</li> </ul> |                    |                   |                    |                           |                 |                                    |                                   |                            |

| Risk No.                         | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------------------------------|---|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| <b>Other Incidental Findings</b> |   |  |                    |                   |                    |                           |  |                                    |                                   |                            |
| 8.                               | <p><b>What:</b><br/>Permanent loss of function for the patient unrelated to the underlying illness.</p> <p><b>Due to:</b><br/>The IMRIS ORT100 Operating Table has a defective locking pin mechanism on the swivel of the base that allows limited free movement of the table top even when locked into position.</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unwanted / incorrect movement in the operating table.</li> <li>• Incorrect diagnosis</li> <li>• Error in surgery of the patient.</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> | <ul style="list-style-type: none"> <li>• Moving the operating table top until it is fixed in position after the locking mechanism is applied.</li> </ul> | Major              | Almost certain    | Exposure           |                           | <ul style="list-style-type: none"> <li>• Supplier / manufacturer is "releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock".</li> <li>• Supplier / manufacturer to fit new entire locking mechanism.</li> <li>• Health Directorate as part of duty of care to notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</li> </ul> | Major                              | Unlikely                          | High                       |



|          |    |  |   |   |   |   |  |  |  |   |  |
|----------|----|--|---|---|---|---|--|--|--|---|--|
| Risk No. | 9. | <p><b>Risk Description</b><br/>What can happen and how</p> <p><b>What:</b><br/>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Unclear responsibility for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>Staff without appropriate training and endorsement by the manufacturer interchanging the IMRIS Operating Table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect operation in the MRI Neurosuite equipment.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> | <p><b>Current Controls</b><br/>What do you already do to mitigate the risk?</p> | <p><b>Consequence Rating</b></p> <p>Major</p> | <p><b>Likelihood Rating</b></p> <p>Almost certain</p> | <p><b>Current Risk Level</b></p> <p>Extreme</p> | <p><b>Acceptability</b><br/>Yes / No</p> | <p><b>Risk Treatments</b></p> <ul style="list-style-type: none"> <li>Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>Appropriate training and endorsement by the manufacturer of the maintenance staff and other staff for the MRI Neurosuite, including the IMRIS ORT100 Operating Table</li> <li>Provide manufacturer manuals for the maintenance and upkeep of the IMRIS ORT100 Operating Table.</li> </ul> | <p><b>Consequence Rating after Treatment</b></p> <p>Moderate</p> | <p><b>Likelihood Rating after Treatment</b></p> <p>Unlikely</p> | <p><b>Risk Level after Treatment</b></p> <p>Medium</p> |
|----------|----|--|---|---|---|---|--|--|--|---|--|

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 10.      | <p><b>What:</b><br/>Shortage of operating theatres at TCH fitted with appropriate medical equipment contributing to backlog in surgical operations.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Incompatible operating theatres to the requirements of the surgeons / theatre staff.</li> <li>Limited use of operating theatres due to old theatre pendants, theatre lights and communication cables.</li> <li>The MRI Neurosuite is required to be left "Ready To Scan" at the end of each day.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Backlog in surgery cases.</li> <li>No spare operating theatre for shutdown of other theatres to allow replacing the theatre pendants, lights and cabling work; they require updating and making safer.</li> </ul> | <ul style="list-style-type: none"> <li>The two Jackson Spinal operating tables are presently used in the other operating theatres.</li> <li>Daily operating theatre scheduling with little or no spare capacity.</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed. Estimated to take 16 working days shutdown for each two operating theatres to do the updating work. It would require 4 (set of 2 theatres) x 16 = 64 working days to complete this previously planned work.</li> <li>Negotiate agreement with other surgical service providers to facilitate surgery during the remediation work, e.g. Royal Darwin Hospital used portable operating theatres installed on-site from the Defence Department.</li> <li>Re-evaluate interchanging the IMRIS Operating Table after the operating theatre pendants have been replaced in all the other theatres.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 11.      | <p><b>What:</b><br/>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Ferrous objects attracted to the magnet.</li> <li>Leaving small metal items or fragments after surgery in the MRI Neurosuite that will be attracted to the magnet when it starts to function, such as pins, screws, metal thread and fragments from implants.</li> <li>Likelihood of occurrence increase if this theatre is used for some other surgical procedures, e.g. implants, orthopaedic.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unclear images.</li> <li>Injury to staff</li> </ul> |  | Moderate           | Possible          | Medium             |                           | <ul style="list-style-type: none"> <li>Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this theatre, including the cleaning, technical and clinical staff.</li> <li>Schedule appropriate surgical cases for this theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</li> <li>Conduct a metal sweep with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

**Kirchner, Horst**

---

**From:** [REDACTED]  
**Sent:** Thursday, 18 August 2011 12:48 PM  
**To:** Kirchner, Horst; Van Lith, Martin; Richard Barroso  
**Subject:** Re: IMRIS Table

Horst. Yesterday I asked my CSS Richard Barroso in Melbourne to contact James Cotterill to arrange a visit to fix your table. I have copied Richard on this email. Richard can you please let Horst know when you have arranged the visit.

Best Regards.

---

**From:** Kirchner, Horst [<mailto:Horst.Kirchner@act.gov.au>]  
**Sent:** Wednesday, August 17, 2011 04:55 PM  
**To:** Van Lith, Martin <[Martin.VanLith@act.gov.au](mailto:Martin.VanLith@act.gov.au)>  
**Cc:** [REDACTED]  
**Subject:** RE: IMRIS Table

Martin, nothing, yes will

*Horst Kirchner*  
 Business & Infrastructure  
 Strategic Support  
 Bldg. 6, L3, TCH  
 62050363

mob. [REDACTED]

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*Care Excellence Collaboration Integrity*




---

**From:** Van Lith, Martin  
**Sent:** Wednesday, 17 August 2011 4:51 PM  
**To:** Kirchner, Horst  
**Subject:** IMRIS Table

Hello Horst

Any response from IMRIS yet? Would you please follow them up?

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure — committed to timely, responsive and*  
*client-focused services*

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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---

**From:** Kirchner, Horst  
**Sent:** Thursday, 11 August 2011 2:36 PM  
**To:** [REDACTED]

Cc: [REDACTED] Van Lith, Martin

Subject: locking

[REDACTED]  
I am concerned about the table locking device, what progress is there on the replacement.  
The lock is not very secure.

regards

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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---

**From:** Kirchner, Horst

**Sent:** Friday, 24 June 2011 8:29 AM

**To:** 'Lindley Ward'

**Subject:** RE:

[REDACTED] thanks for the update.

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob. [REDACTED]*

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---

**From:** [REDACTED]

**Sent:** Thursday, 23 June 2011 10:36 PM

**To:** Kirchner, Horst

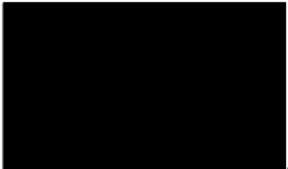
**Subject:** RE:

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We are in the process of releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock. The parts are going into production next week, so I will soon have a date for the delivery of the parts to my group for implementation. The updates will be scheduled with each customer once I have the delivery dates for the parts.

Best Regards,





**From:** Kirchner, Horst [mailto:Horst.Kirchner@act.gov.au]  
**Sent:** June-22-11 9:59 PM  
**To:** [Redacted]  
**Subject:**

[Redacted] We are taking the table of the floor today, I noticed that the locking pin (picture) was quite loose, this does not seem right, as the table moves when locked?.

cheers

*Horst Kirchner*  
*Business & Infrastructure*  
*Strategic Support*  
*Bldg. 6, L3, TCH*  
*2050363*

mob. [Redacted]

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**McClymont, Geoff**

---

**From:** Van Lith, Martin  
**Sent:** Thursday, 18 August 2011 2:19 PM  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst  
**Subject:** FW: IMRIS Table

Hello Jennie

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This fix is for the locking mechanism at the base of the table. At present the mechanism does not work effectively and allows limited free movement of the table top; an extreme risk for a neuro-surgery table.

TGA needs to be informed of the product correction. Can James ask IMRIS if this is already in progress please?

Horst and I will now step back from this part of the issue and let IMRIS work with James to do the fix.

Kind regards

**Martin Van Lith**

Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and client-focused services*

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

*Care Excellence Collaboration Integrity*

---

**From:** [REDACTED]  
**Sent:** Thursday, 18 August 2011 12:48 PM  
**To:** Kirchner, Horst; Van Lith, Martin; Richard Barroso  
**Subject:** Re: IMRIS Table

Horst. Yesterday I asked my [REDACTED] in Melbourne to contact James Cotterill to arrange a visit to fix your table. I have copied Richard on this email. Richard can you please let Horst know when you have arranged the visit.

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---

**From:** Kirchner, Horst [<mailto:Horst.Kirchner@act.gov.au>]  
**Sent:** Wednesday, August 17, 2011 04:55 PM  
**To:** Van Lith, Martin <[Martin.VanLith@act.gov.au](mailto:Martin.VanLith@act.gov.au)>  
**Cc:** [REDACTED]  
**Subject:** RE: IMRIS Table

Martin, nothing, yes will

*Horst Kirchner*  
 Business & Infrastructure  
 Strategic Support  
 Bldg. 6, L3, TCH  
 62050363  
 mob. [REDACTED]

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**From:** Van Lith, Martin  
**Sent:** Wednesday, 17 August 2011 4:51 PM  
**To:** Kirchner, Horst  
**Subject:** IMRIS Table

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Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
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client-focused services*

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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**From:** Kirchner, Horst  
**Sent:** Thursday, 11 August 2011 2:36 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED] Van Lith, Martin  
**Subject:** locking

[REDACTED]  
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The lock is not very secure.

regards

*Horst Kirchner*  
*Business & Infrastructure*  
*Strategic Support*  
*Bldg. 6, L3, TCH*  
*62050363*  
*mob [REDACTED]*

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**From:** Kirchner, Horst  
**Sent:** Friday, 24 June 2011 8:29 AM  
**To:** [REDACTED]  
**Subject:** RE:

[REDACTED] thanks for the update.

*Horst Kirchner*

Business &amp; Infrastructure

Strategic Support

Bldg. 6, L3, TCH

62050363

mob. [REDACTED]

*Business & Infrastructure — committed to timely, responsive and client-focused services**Care Excellence Collaboration Integrity***From:** Lindley Ward [mailto:lward@imris.com]**Sent:** Thursday, 23 June 2011 10:36 PM**To:** Kirchner, Horst**Subject:** RE:

Horst:

We are in the process of releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock. The parts are going into production next week, so I will soon have a date for the delivery of the parts to my group for implementation. The updates will be scheduled with each customer once I have the delivery dates for the parts.

Best Regards,

**From:** Kirchner, Horst [mailto:Horst.Kirchner@act.gov.au]**Sent:** June-22-11 9:59 PM**To:** [REDACTED]**Subject:**

[REDACTED] we are taking the table of the floor today, I noticed that the locking pin (picture) was quite loose, this does not seem right, as the table moves when locked?.

cheers

*Horst Kirchner*

Business &amp; Infrastructure

Strategic Support

Bldg. 6, L3, TCH

62050363

mob. [REDACTED]

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**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:41 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH  
**Attachments:** Review report 180811.docx

---

**From:** Geoghegan, Sean  
**Sent:** Thursday, 18 August 2011 7:22 PM  
**To:** Van Lith, Martin  
**Subject:** Re: Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

Hi Martin,

my comments are attached. Only one change. I couldn't edit it properly - the citrix connect is very poor and I couldn't adequately work on it. Some of the phrases seem awkward, but it is good as it stands.

Cheers,

Sean

---

Sean Geoghegan, PhD  
 Chief Medical Physicist ACT Health ACT Australia  
 p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
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---

**From:** Van Lith, Martin  
**Sent:** Thursday, 18 August 2011 11:38  
**To:** Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Geoghegan, Sean; Swain, Rob  
**Cc:** Scott, Adrian; Baker, Jennie  
**Subject:** Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

Hello

I was able to speak with Dr John Fuller, Head of Neurosurgery yesterday and obtain his views on the interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH. His comments are included in the report.

A draft report is attached for your review and updating.

Your changes, updates, corrections **back to me by early morning Friday 19 August 2011.**

Kind regards

**Martin Van Lith**



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Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
*Care Excellence Collaboration Integrity*

**Baker, Jennie**

---

**From:** Baker, Jennie  
**Sent:** Friday, 19 August 2011 9:38 AM  
**To:** Cotterill, James  
**Subject:** RE: IMRIS Table

Hi James,

Sounds good to me.

Jennie

---

**From:** Cotterill, James  
**Sent:** Friday, 19 August 2011 9:22 AM  
**To:** Baker, Jennie  
**Subject:** RE: IMRIS Table

Hi Jennie

I think the issue with this table is serious enough to require a recall. I have made complaints to the TGA before and I know you have to push very hard to get them to take action and you also need to be very sure of the information you have. At this stage I have no information to offer... I am just waiting on a confirmation call back from the IMRIS technician. If IMRIS has identified this to be a defect and have issued an internal recall BUT have not reported that to its clients and to the TGA then they may face some serious repercussions from the TGA. I think waiting a few hours so we can get the information we need is the best way forward, at the moment I don't have enough information to correctly complete a TGA complaint form. Once I hear back from the IMRIS technician I will have the correct information and hopefully some documentation to back it up.

Regards

James

---

**From:** Baker, Jennie  
**Sent:** Thursday, 18 August 2011 4:37 PM  
**To:** Cotterill, James  
**Subject:** RE: IMRIS Table

Hi James,

I don't think that he mentions a recall, it is just to let them know that there issues with the system in case other sites have identified the same.

Jennie

---

**From:** Cotterill, James  
**Sent:** Thursday, 18 August 2011 4:28 PM  
**To:** Baker, Jennie  
**Subject:** RE: IMRIS Table

Hi Jennie

It may be premature to contact TGA until we hear back from IMRIS, at this stage IMRIS have not confirmed the existence of a manufacturing defect/recall with the table.

Horst was told by IMRIS they knew about the issue, but I have nothing in writing from IMRIS to confirm this..at this stage.

TGA would need to investigate the fault in order to issue a recall and so we need to get our facts in order before we go down that path.

I believe the best way forward is to wait a few days until we hear back from the service contact at IMRIS, then once we know the facts and have some documentation we can contact TGA.

Regards

James

---

**From:** Baker, Jennie  
**Sent:** Thursday, 18 August 2011 4:18 PM  
**To:** Cotterill, James  
**Subject:** FW: IMRIS Table

Hi James,

Can you please confirm if TGA are aware?

Jennie

---

**From:** Van Lith, Martin  
**Sent:** Thursday, 18 August 2011 2:19 PM  
**To:** Baker, Jennie  
**Cc:** Cotterill, James; Kirchner, Horst  
**Subject:** FW: IMRIS Table

Hello Jennie

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TGA needs to be informed of the product correction. Can James ask IMRIS if this is already in progress please?

Horst and I will now step back from this part of the issue and let IMRIS work with James to do the fix.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and  
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---

**From:** [REDACTED]  
**Sent:** Thursday, 18 August 2011 12:48 PM

**To:** Kirchner, Horst; Van Lith, Martin; Richard Barroso  
**Subject:** Re: IMRIS Table

Horst. Yesterday I asked my CSS Richard Barroso in Melbourne to contact James Cotterill to arrange a visit to fix your table. I have copied Richard on this email. Richard can you please let Horst know when you have arranged the visit.

Best Regards.

[Redacted]

---

**From:** Kirchner, Horst [mailto:Horst.Kirchner@act.gov.au]  
**Sent:** Wednesday, August 17, 2011 04:55 PM  
**To:** Van Lith, Martin <Martin.VanLith@act.gov.au>  
**Cc:** Lindley Ward  
**Subject:** RE: IMRIS Table

Martin, nothing, yes will

*Horst Kirchner*  
*Business & Infrastructure*  
*Strategic Support*  
*Bldg. 6, L3, TCH*  
*62050363*  
*mob. [Redacted]*

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---

**From:** Van Lith, Martin  
**Sent:** Wednesday, 17 August 2011 4:51 PM  
**To:** Kirchner, Horst  
**Subject:** IMRIS Table

Hello Horst

any response from IMRIS yet? Would you please follow them up?

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**From:** Kirchner, Horst  
**Sent:** Thursday, 11 August 2011 2:36 PM  
**To:** [Redacted]  
**Cc:** [Redacted] Van Lith, Martin  
**Subject:** locking

[Redacted]

I am concerned about the table locking device, what progress is there on the replacement.

The lock is not very secure.

regards

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob.* [REDACTED]

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---

**From:** Kirchner, Horst

**Sent:** Friday, 24 June 2011 8:29 AM

**To:** [REDACTED]

**Subject:** RE:

[REDACTED] thanks for the update.

*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob.* [REDACTED]

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**From:** [REDACTED]

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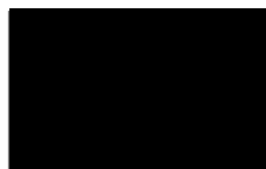
**To:** Kirchner, Horst

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Best Regards,





**From:** Kirchner, Horst [mailto:Horst.Kirchner@act.gov.au]

**Sent:** June-22-11 9:59 PM

**To:** [REDACTED]

**Subject:**

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*Horst Kirchner*

*Business & Infrastructure*

*Strategic Support*

*Bldg. 6, L3, TCH*

*62050363*

*mob [REDACTED]*

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**Baker, Jennie**

---

**From:** Baker, Jennie  
**Sent:** Friday, 19 August 2011 10:15 AM  
**To:** Cotterill, James  
**Subject:** RE: IMRIS theatre table

Hi James,

Could you please ensure that TGA are informed?

Jennie

---

**From:** Cotterill, James  
**Sent:** Friday, 19 August 2011 10:14 AM  
**To:** Baker, Jennie  
**Cc:** Williams, Horace; Kirchner, Horst; Belle, Kyril; Sommariva, Maurice; Thorburn, Phillip; Geoghegan, Sean; Saker, Steve; Hallberg, Erik; Van Lith, Martin  
**Subject:** IMRIS theatre table

Good morning,

I received a call this morning from [REDACTED] one of the field technicians from IMRIS Australia. [REDACTED] said he has a tentative booking to travel to Canberra next Monday to check the table and make some temporary repairs. He is currently waiting on a call back from Rhona to confirm a time.

[REDACTED] has confirmed that the table is subject to a factory field upgrade and that IMRIS recognises the problem is a manufacturing fault. Unfortunately the upgrade kit is not in the country as yet, but when it arrives (1-2 weeks) [REDACTED] will return to TCH and install it.

I have advised [REDACTED] that there is a requirement for IMRIS to inform the TGA about this matter and that TCH is required to do the same.

Regards

**James Cotterill**  
Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**Baker, Jennie**

---

**From:** Van Lith, Martin  
**Sent:** Friday, 19 August 2011 10:31 AM  
**To:** Cotterill, James  
**Cc:** Scott, Adrian; Baker, Jennie  
**Subject:** RE: IMRIS theatre table

Hello James

Many thanks.

May be a good time to talk to him about the training for the maintenance of the table. Do you have all the maintenance manuals for the table?

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and client-focused services*

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**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**McClymont, Geoff**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:40 PM  
**To:** McClymont, Geoff  
**Subject:** IMRI FOI - FW: Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

---

**From:** Van Lith, Martin  
**Sent:** Friday, 19 August 2011 9:47 AM  
**To:** Geoghegan, Sean  
**Subject:** RE: Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

Thanks Sean

Much obliged. We are finalising the report. Adrian wanted it with recommendations.

Kind regards

**Martin Van Lith**



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**From:** Geoghegan, Sean  
**Sent:** Thursday, 18 August 2011 7:22 PM  
**To:** Van Lith, Martin  
**Subject:** Re: Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

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Cheers,

Sean

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Sean Geoghegan, PhD  
 Chief Medical Physicist ACT Health ACT Australia  
 p: +61 2 6244 2256 f: +61 2 6244 2276 m: [REDACTED]  
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---

**From:** Van Lith, Martin  
**Sent:** Thursday, 18 August 2011 11:38  
**To:** Thorburn, Phillip; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Geoghegan, Sean; Swain, Rob  
**Cc:** Scott, Adrian; Baker, Jennie  
**Subject:** Interchange of the IMRIS operating theatre table in the MRI Neurosuite at TCH

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**McClymont, Geoff**

---

**From:** [REDACTED]  
**Sent:** Sunday, 21 August 2011 2:28 PM  
**To:** Cotterill, James  
**Subject:** RE: Manufacturing defect IMRIS MRI table  
**Attachments:** T300032-000 Rev G.pdf

Resend...bounced back to me.

---

**From:** [REDACTED]  
**Sent:** August-18-11 11:42 PM  
**To:** 'Cotterill, James'  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

Sure its not a problem.... but did something happen with the IMRIS service guys as they should still be coming to fix the table. I realize warranty has expired but we were going to get that resolved when Alan Ringland gets back from leave (we would just backdate the service contract).

For now , all I have on my laptop is the attached. Please let me know if the IMRIS service guys are not coming and I will investigate. If the guys are coming do you still want the service manual

Best Regards,  
[REDACTED]

---

**From:** Cotterill, James [<mailto:James.Cotterill@act.gov.au>]  
**Sent:** August-18-11 8:05 PM  
**To:** [REDACTED]  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi [REDACTED]

was wondering if we could be sent a service manual for the OT100?  
Since our warranty is now null and void it appears we will need to service the table.

Regards

James Cotterill  
Biomedical Engineering  
Canberra Hospital

---

**From:** [REDACTED]  
**Sent:** Wednesday, 17 August 2011 11:37 AM  
**To:** Cotterill, James  
**Cc:** Richard Barroso; Michael Thomas  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

[REDACTED] who are currently in Melbourne (on the RCH install) will be contacting you shortly to arrange a time to come.

Best Regards,

**IMRIS** 

M. 204 291 6707 (Canada)  
 M. 03 9005 6799 (Australia)  
 M. 70 7847 7036 (South Korea)  
 M. 852 8199 9245 (Hong Kong)  
 E. [REDACTED]  
[www.imris.com](http://www.imris.com)

---

**From:** Cotterill, James [<mailto:James.Cotterill@act.gov.au>]  
**Sent:** August-16-11 8:17 PM  
**To:** [REDACTED]  
**Subject:** Manufacturing defect IMRIS MRI table

To: [REDACTED]  
 IMRIS Australia

You may recall we were in contact a few weeks ago regarding the removal of the IMRIS table at the Canberra Hospital.  
 Now we have another issue... upon installation of the table last week we noticed the table itself was unstable. The problem was found to be related to the manual locking mechanism which allows the table be unlocked and rotated up to 180 degrees.  
 There appears to be a manufacturing defect in this locking mechanism which allows too much free play..as a consequence the table can move sideways.  
 As you can imagine this poses a serious risk to patient safety, accordingly we, Biomedical Engineering are advising our staff not to use the table until it has been repaired.

I was made aware that IMRIS was also aware of this issue and is producing a in the field upgrade kit. Could you please let me know when our table could be fitted with the upgrade.

Many thanks

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
 Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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This email has been scanned by the IMRIS Email Security System

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This email has been scanned by the IMRIS Email Security System.

This email has been scanned by the IMRIS Email Security System

**McClymont, Geoff**

---

**From:** Cotterill, James  
**Sent:** Monday, 22 August 2011 8:17 AM  
**To:** [REDACTED]  
**Subject:** RE: Manufacturing defect IMRIS MRI table

[REDACTED]

Thank you, we just like to have service manuals for all of the assets we have, the question was raised if we had a manual or not when a discussion arose regarding the in house servicing of the table  
If you could send the service manual it would be appreciated.

Regards James

---

**From:** [REDACTED]  
**Sent:** Sunday, 21 August 2011 2:28 PM  
**To:** Cotterill, James  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Resend...bounced back to me.

---

**From:** [REDACTED]  
**Sent:** August-18-11 11:42 PM  
**To:** 'Cotterill, James'  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

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[REDACTED]

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Biomedical Engineering  
Canberra Hospital

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**Subject:** RE: Manufacturing defect IMRIS MRI table

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Best Regards,  
[REDACTED]

---

[REDACTED]



M. 204 291 6707 (Canada)  
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M. 70 7847 7036 (South Korea)  
M. 852 8199 9245 (Hong Kong)  
E. [REDACTED]  
[www.imris.com](http://www.imris.com)

---

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**Sent:** August-16-11 8:17 PM  
**To:** [REDACTED]  
**Subject:** Manufacturing defect IMRIS MRI table

To: [REDACTED]  
IMRIS Australia

[REDACTED]

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Many thanks

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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This email has been scanned by the IMRIS Email Security System

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This email has been scanned by the IMRIS Email Security System.

This email has been scanned by the IMRIS Email Security System



**McClymont, Geoff**

---

**From:** Cotterill, James  
**Sent:** Monday, 22 August 2011 11:53 AM  
**To:** Van Lith, Martin  
**Subject:** FW: IMRIS OR table Materials #2  
**Attachments:** IMRIS OR Table.pptx

---

**From:** [REDACTED]  
**Sent:** Saturday, 6 August 2011 11:38 AM  
**To:** Cotterill, James  
**Subject:** RE: IMRIS OR table Materials #2

Here is a presentation of the OR table with some procedural stats from other hospitals.

---

**From:** [REDACTED]  
**Sent:** August-05-11 8:33 PM  
**To:** 'james.cotterill@act.gov.au'  
**Subject:** IMRIS OR table Materials #1

Hi James,

I have attached a basic user manual for the OR table and will also try to include some reference materials to help aid the discussion. As I mentioned our spine capabilities are limited but possible...I will also send materials in a couple of e-mails due to file size.

1. Our system has been used clinically for cervical spine work by Dr. Garnette Sutherland Foothills Hospital Calgary (Canada), and Dr. Carlo DeLuna Wilkes Barre General hospital (USA). They have successfully used the system for ACDF's, cervical tumors, and trans-oral decompressions. Please note that they have made concessions to do these surgeries such as make shift equipment that their hospital made for them.
2. Dr. David Donahue and Dr. John Honeycut of Cook Children's have used the system intra-operatively on a tethered chord case. They have also worked in the base of the skull/top of the spine for Chiari malformations.
3. Currently it is extremely challenging to use our system for lumbar spine or thoracic spine work. Making a table extension would only work when the patient was positioned flat and we could get the MRI low enough to scan. The only other option would be to get a knee chest position and get the MRI low enough to image.

Best Regards,  
 [REDACTED]



**Baker, Jennie**

---

**From:** Van Lith, Martin  
**Sent:** Monday, 22 August 2011 12:36 PM  
**To:** Scott, Adrian; Reid, Barbara  
**Cc:** Baker, Jennie; Lang, Kellie; Cotterill, James  
**Subject:** IMRIS Operating Theatre Table

Hello Barbara and Adrian

I have looked at the Procurement document for the integrated neurosurgical operating suite with IMRIS and it states on page 3.5 that "The table is bolted to the OR floor ....."

The IMRIS Australia field technician, Michael Thomas, is driving from Sydney to Canberra at this moment and will be at TCH this afternoon. He will be making contact with James Cotterill in biomedical engineering and the operating theatre.

The purpose of this visit is to look at the problem with the locking mechanism of the table and make a temporary 'fix' until the 'permanent fix' arrives in a few weeks from Canada.

Contacted the manufacturer and they are happy to talk to us this Wednesday by telephone.



M. 204 291 6707 (Canada)  
M. 03 9005 6799 (Australia)  
M. 70 7847 7036 (South Korea)  
M. 852 8199 9245 (Hong Kong)  
E.   
[www.imris.com](http://www.imris.com)

In the meantime Jeff would like to know the type of surgical procedures to be used for the table; e.g. is it just a longer table or a table that bends

Jeff will advise the suitable time for the telephone call after I send him further information on the requirements.

Looking forward to your response on the surgical requirements for the theatre table.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
***Business and Infrastructure – committed to timely, responsive and client-focused services***

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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**Baker, Jennie**

---

**From:** Geoghegan, Sean  
**Sent:** Monday, 22 August 2011 12:58 PM  
**To:** Shaw, Diane  
**Cc:** Cotterill, James; Baker, Jennie  
**Subject:** RE: IMRIS table

Hi Di,

I understand that you need the IMRIS table lifted in preparation for the theatre case tomorrow morning. I just tried to call but was unable to reach you. I spoke to James Cotterill from Biomedical Engineering about the request to lift the IMRIS table. He is the person who will organise the lift for you. Please call James on 43831 to make the arrangements.

The table lift will need to wait until after the table has been serviced in-situ by the engineer from IMRIS this afternoon. That will mean that the table will not be lifted before about 17:00 at the earliest. It may be that the table will need to be left in-situ after servicing, however I expect that the likelihood of this is remote and the table should be able to be lifted and put into storage by about 18:00. James will be able to confirm the details and confirm the timing of the lift.

As discussed, once the table is lifted and taken out it will not be going back in without written authorisation from Barbara Reid.

Cheers,

Sean

Sean Geoghegan  
Chief Medical Physicist    Medical Physics and Medical Technology Systems  
Phone: 6244 2256 | Mobile: [REDACTED] Fax: 6244 3819 | Email:  
[sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)

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-----Original Message-----

From: Shaw, Diane  
Sent: Monday, 22 August 2011 12:42 PM  
To: Geoghegan, Sean  
Subject:

Sean  
Further to our phone conversation re lifting the iMRI table this pm after maintenance can you please phone me or Angela Goodridge on [REDACTED] or 42765 and ask for patient flow CNC re time for lifting the table Thanks

Diane Shaw  
Acting Patient Flow CNC  
Level 2 General Surgery  
Operating Theatres  
The Canberra Hospital  
Yamba Drive  
ACT 2606  
62442765  
[Diane.Shaw@act.gov.au](mailto:Diane.Shaw@act.gov.au)



**Business & Infrastructure Branch**  
with support from  
**Surgery and Oral Health Division**  
**&**  
**Quality and Safety Unit**

**Review**

**Interchange of IMRIS Operating Table in the MRI  
Neurosuite at TCH**

**Final Report**

22 August 2011

## **Executive Summary**

The review set out to develop a risk management plan and identify key risks associated with the frequent interchange (removal and re-installation) of the IMRIS Operating Table in the MRI Neurosuite at TCH following various concerns associated with interchanging of the Table.

The IMRIS Operating Table has been interchanged to make way for other operating theatre tables so that the operating theatre can be used for other surgical procedures.

The IMRIS Operating Table was supplied and fixed to the floor as part of the installation of the MRI Neurosuite during 2010. The supplier and manufacturer is Intra-Operative Magnetic Resonance Imaging System (IMRIS) Inc. based in Canada.

The review considered the risks for interchanging the IMRIS Operating Table and also for leaving it in position. The review process uncovered other important and closely related risks.

The identified key risks were analysed, current controls identified, assessed and risk treatments proposed to lower the risk levels.

Recommendations were based on the proposed risk treatments for interchanging the IMRIS Operating Table and also for leaving it in position.

### **1. Report Owner**

The review was initiated and the report is owned by the Business & Infrastructure Branch Executive Director, currently acting in this position is Mr Adrian Scott.

The review team included:

Martin Van Lith - Coordinator, Accreditation & Risk Management, Business & Infrastructure Branch.

Phil Thorburn – Biomedical Engineer, Redevelopment Unit, Service & Capital Planning

Rhona JasonSmith - Assistant Director of Nursing Perioperative Services

Horst Kirchner - Project Manager, Strategic Asset Management & Accommodation

James Cotterill - Biomedical Engineering Technician, Clinical Engineering

Sean Geoghegan - Chief Medical Physicist, Medical Physics and Medical Technology Systems

Rob Swain - Assistant Director, Workplace Safety, Quality & Safety Unit

### **2. Review Objectives and Scope**

The objectives of the review team were to:

- Establish the facts with the interchange of the IMRIS Operating Room Table using Risk Analysis
- Provide a report of the review findings and formulate recommendations
- Look for system gaps and opportunities for improvement

The scope of the review included the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

### 3. Review Process

The review process consisted of:

- A documentation review including related Emails and Product Manuals;
- Site visits and demonstration of the re-installation;
- Interviews with key stakeholders;
- Analysis of findings utilising risk analysis;
- Reporting of the findings and recommendations; and
- A risk analysis to support the report (Attachment A).

A telephone discussion was held with Dr John Fuller, Head of Neurosurgery, on 17 August 2011. He stated that the MRI Neurosuite should be used more often as an operating theatre and not wasted. He also stated that as a surgeon he considered that the IMRIS Operating Table was not suitable for other surgery. His opinion was that the operating theatre should be used and that it required the IMRIS Operating Table be moved to make way for other operating theatre tables.

### 4. Summary of Key Risks and Recommendations

The review found that most interviewed stakeholders were concerned over the governance, management and safety associated with the frequent interchange (removal and re-installation) of IMRIS Operating Table in the MRI Neurosuite at TCH.

The Risk Management Plan in Attachment A contains the key risks that fell into the following main categories:

- Clinical
- People
- Property and Services
- Financial
- Business Process and Systems
- Reputation



## Key Risks and Recommendations

| Risks   | Recommendation   |
|---|--|
| <ul style="list-style-type: none"> <li>• The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</li> <li>• All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS Operating Table, has been moved from the manufacture and installer to the Health Directorate.</li> <li>• Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</li> <li>• Interchanging the IMRIS Operating Table causes premature 'wear and tear', as well increases the chance for error during each installation.</li> <li>• Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</li> </ul> | <p>1.1 Do not interchange the IMRIS ORT100 Operating Table in the MRI Neurosuite.</p> <p>OR</p> <p>1.2 If the IMRIS ORT100 Operating Table is to be interchanged then implement the risk treatments outlined in the Risk Management Plan</p> <p>1.3 Investigate with IMRIS designing a removable Operating Table suitable for use in the MRI Neurosuite and/or an interchangeable Operating Table top.</p> |
| <p>Permanent loss of function for the patient unrelated to the underlying illness.</p>  | <p style="text-align: center;"><b>Recommendation</b></p> <p>2.1 Supplier / manufacturer to fit a new entire locking mechanism to the IMRIS ORT100 Operating Table.</p> <p>2.2 Health Directorate notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</p>   |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p>   | <p>3.1 Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</p> <p>3.2 Appropriate training and endorsement by the manufacturer for the maintenance staff &amp; other staff for the IMRIS ORT100 Operating Table.</p>  |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p>  | <p>4.0 Modify operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding existing theatre light.</p>  |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>The MRI Neurosuite not being fully utilised for surgery.</p>   | <p>5.1 Utilise the IMRIS ORT 100 Operating Table into the least obstructive position when using other operating theatre tables,<br/>AND / OR</p> <p>5.2 Regulate the use of the MRI Neurosuite to surgical procedures that can be performed on the IMRIS ORT 100 Operating Table.</p>  |

| Risk  | Recommendation   |
|---|--|
| Operating theatres at TCH not fitted with appropriate medical equipment contributing to backlog in surgical operations.                             | 6.0 Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed.  |
| Risk  | Recommendation   |
| Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant <u>small metal items or fragments</u> | <p>7.1 Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this operating theatre, including the cleaning, technical and clinical staff.</p> <p>7.2 Schedule appropriate surgical cases for this operating theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</p> <p>7.3 Conduct a metal sweep of the operating theatre with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</p> |

*HK comment Nov.*

This was a one off incident when ~~the~~ one screw holding the base cover needed to be re-threaded because the initial installation was cross threaded. When we re-threaded we had not cleaned up the steel shavings! (this was going to be cleaned before we handed the table back, and then a theatre team would have cleaned up anyway) to say that there could be loose metal after a removal or instal is foolish.

## 5. Conclusion

The risk management plan identified key risks associated with the frequent interchange (removal and re-installation) and also for leaving fixed the IMRIS Operating Table in the MRI Neurosuite at TCH. The process also highlighted other important and closely related risks.

The risk management planning process identified three extreme level, six high level and two medium level risks.

Expedient attention is urged to address the following three extreme level risks.

1. It is recommended that the IMRIS ORT100 Operating Table not be interchanged. The review identified an extreme risk associated with interchanging the IMRIS ORT100 Operating Table from the adverse effect on the correct and accurate function of the table, premature 'wear and tear', increased chance for error during installation, increased liability and possibility to increased litigation exposure, as well as staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate.

If the IMRIS ORT100 Operating Table is to be interchanged then it is recommended that the risk treatments outlined in the Risk Management Plan under Risk Nos. 1, 2, 3 4 and 5 be implemented.

2. It is recommended that the supplier/manufacture of the IMRIS ORT100 Operating Table fits a new entire locking mechanism and that the Therapeutic Goods Administration (TGA) be notified of the problem with the Table. Limited free movement of the Table top presents an extreme risk from permanent loss of function for the patient unrelated to the underlying illness.
3. It is also recommended that responsibility and appropriate resources be allocated, including ongoing costs, for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table. Appropriate training is required and endorsement by the manufacturer for the maintenance staff & other staff for the IMRIS ORT100 Operating Table.

Recommendations 4.0, 5.1, 5.2, 6.0, 7.1, 7.2 and 7.3 listed in the Table above also apply and are presented for follow-up and action to lower the other high and medium risks identified during the review.



# RISK MANAGEMENT PLAN

**Title (Project / Activity / Program):** Interchange of IMRIS Operating Table in the MRI Neurosuite at TCH **File No:** .....

**Objective / Background:** Developing a risk management plan and identifying any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

**Prepared by:** Martin Van Lith, Phil Thorburn, Sean Geoghegan, Rhona JasonSmith, Horst Kirchner, James Cotterill, Rob Swain **Date:** 22 August 2011  
**Reviewed by:** Adrian Scott, Barbara Reid **Date:** 22 August 2011

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|---|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 1        | <p><b>What:</b><br/>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>There are many mechanical parts, such as screws, at the base plate involved in the</li> </ul> | <ul style="list-style-type: none"> <li>A dedicated toolkit and parts list has been made for the interchange.</li> <li>A written procedure containing illustrative photographs has been drafted and tested.</li> <li>Workplace safety analysis has been made and issues addressed</li> <li>IMRIS has been consulted throughout the project.</li> <li>Cleaning operating procedure developed and tested.</li> </ul> | Major              | Almost certain    | High               | Yes                       | <ul style="list-style-type: none"> <li>Develop responsibility and training of staff for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Use a checklist for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Checklist to be used by the installation staff and a separate list by the spotter. Verify lists and sign off at the end of installation.</li> <li>Use one independent</li> </ul> | Major                              | Possible                          | High                       |

603

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment  | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|--|---|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>interchange of the IMRIS operating table.</li> <li>Responsibility and training of staff for the removal and re-installation not clear.</li> <li>The two hydraulic lines and connectors in the floor are thin walled solid metal tubing AND are flexed each time the table is moved. They are held in a flexed position under the cover plate. The stainless steel tubing will caseharden over time in the flexed (stressed) position and is almost certain to crack. The hydraulic lines are also more vulnerable to damage if the table is moved on a regular basis.</li> <li>The hydraulic system is at very high pressure and the connector fittings are not designed for a large number disconnections and reconnections to be made and is almost certain to fail after a finite number of installations.</li> <li>Every time the table is moved a small amount of oil leaks out and the possibility can arise where air bubbles may become trapped within the lines. The trapped air can then travel</li> </ul> | <ul style="list-style-type: none"> <li>A purpose built lifting device has been procured to lift, move and support the table during storage when not in use.</li> </ul> |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>person as a spotter during removal and re-installation.</li> <li>Independent check each time of the re-installation of the IMRIS ORT100 Operating Table, e.g. mechanical, electrical, alignment, functions of the theatre table, verification of two checklists.</li> <li>Review the mechanical loading capability of the side rails of the IMRIS ORT 100 Operating Table to support its own weight indefinitely and provide a supporting base to the table when in storage if required.</li> <li>Re-engineer the base of the table to allow reliable reconnection of the hydraulic system and increased durability of the connecting tubes.</li> <li>Re-engineer the covers and underlying screw holes to allow reliable refitting of the covers without the generation of filings.</li> </ul> | <p>Done</p> <p>Done</p> <p>connected from IMRIS said OK</p> <p>7 days</p> <p>about pipe</p> | <p>IMRIS</p>                      |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
|          | <p>throughout the hydraulic circuit.</p> <ul style="list-style-type: none"> <li>Electrical wire connections need to be applied correctly.</li> <li>Potential for dirt and metal filings to remain in the operating theatre after the interchange</li> <li>The concrete supporting the base of the table is cracked by the repeated application and removal of loading stress making the base unstable.</li> <li>The screw holes are not aligned with the holes on the cover plates leading to the screw holes needing to be tapped or the cover plates modified (this has a current frequency of about 1 every 3 to 4 reinstalls).</li> <li>The side rails, used to support the table on the table lift when the table is not in use and in storage, fail due to the continual load being placed on the rails.</li> <li>The time pressure to complete the re-installation of the table leading to errors in reassembly of components of the table.</li> </ul> |  |                    |                   |                    |                           | <ul style="list-style-type: none"> <li>Schedule the removal and reinstallation of the table allowing at least two hours for the process prior to any cleaning or preparation of the theatre for a clinical case.</li> </ul> |                                    |                                   |                            |

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| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unwanted / incorrect movement in the operating table.</li> <li>• Production of metallic filings and the inadvertent deposition of other mobile magnetisable objects which interfere with the MRI magnetic field or act as projectiles when the magnet is moved into the operating theatre.</li> <li>• Damage to the table.</li> <li>• Injury to a bystander (staff or patient).</li> <li>• If the hydraulic lines did fail and there is a sudden loss of hydraulic pressure the effect 'could' be unwanted movement of the table bed and that 'could' create a life threatening situation.</li> <li>• Incorrect diagnosis</li> <li>• Error in surgery of the patient.</li> <li>• Permanent loss of function for the patient unrelated to the underlying illness.</li> <li>• Repairs to the hydraulic lines would be an expensive and lengthy process.</li> </ul> | <p>X</p> <p>X</p> <p>X</p>                                       |                    |                   |                    |                        |                 |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <ul style="list-style-type: none"> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> <p><b>What:</b><br/>All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directorate.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table is part of the MRI machine as an integrated and calibrated system in the Neurosuite.</li> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>Health Directorate modifying the IMRIS operating table.</li> <li>The purpose of the IMRIS operating table has been changed from fixed equipment to interchangeable.</li> <li>The local IMRIS representative does <i>not</i> support the interchange of the IMRIS</li> </ul> | Not adequately addressed   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>IMRIS re-install and certify the ORT100 operating table may reduce this liability</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 3        | <p>operating table and warns against such action.</p> <ul style="list-style-type: none"> <li>Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Legal liability</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> <p><b>What:</b><br/>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Supplier knows that Health Directorate is interchanging the IMRIS Operating Table and advised against it.</li> <li>Health Directorate have chosen to use the IMRIS Operating Table outside its design parameter.</li> <li>Removing the IMRIS Operating Table has voided the manufacturer's warranty and</li> </ul> | <ul style="list-style-type: none"> <li></li> </ul>               | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Seek legal opinion.</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 4        | <p>introduced the possibility for a range of risk and liabilities</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Legal liability</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> <li>• Reputation loss</li> </ul> <p><b>What:</b><br/>Interchanging the IMRIS operating table causes premature 'wear and tear', as well as increases the chance for error during each installation.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Written procedure for interchanging the IMRIS operating table not being followed.</li> <li>• Moving the operating table on a regular basis increases wear and tear on the connecting parts.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Extra costs</li> <li>• Interference with theatre booking schedule</li> </ul> | <ul style="list-style-type: none"> <li>• Written operating procedure</li> <li>• Two people installing and one person observing.</li> <li>• Final check and signoff by an independent person following checking the reinstallation.</li> <li>• Written procedures for cleaning</li> <li>• Magnet roller check for metals</li> </ul> | Moderate           | Possible          | Medium             |                        | <ul style="list-style-type: none"> <li>• Investigate with IMRIS designing a removable Operating Table suitable for use in the MRI Neurosuite and/or an interchangeable Operating Table top.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 5        | <p><b>What:</b><br/>Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Metal cover plate is a trip hazard to staff and mobile equipment in the theatre.</li> <li>• The 'hump' in the metal cover plate presents a hazard if the operating table is moved with a patient.</li> <li>• Busy work environment</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Damage to staff or patients.</li> <li>• Costs</li> </ul> | <ul style="list-style-type: none"> <li>• Workplace safety assessment has been conducted with staff from Workplace Safety and with operating theatre staff.</li> <li>• An operating theatre table to be located over the metal cover plate during use of theatre.</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Ensure that the metal cover plate has an operating theatre table or other large equipment located over it at all times and does not present a trip hazard.</li> </ul> | Major                              | Unlikely                          | High                       |
| 6        | <p><b>What:</b><br/>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p> <p><b>Due to:</b></p>   |   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Modifying operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding exiting theatre light.</li> </ul>                             | Major                              | Rare                              | Medium                     |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>The configuration and location of the theatre lights does not provide as effective lighting of the surgical sites when used outside the allocated area for the fixed IMRIS Operating Table.</li> <li>The Jackson Spinal operating theatre table is longer than a normal operating table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Inadequate lighting of the surgical site.</li> <li>Injury to patient</li> <li>Modification of the operating theatre light required for the MRI Neurosuite.</li> <li>Extra costs</li> </ul> |  |                    |                   |                    |                           |                 |                                    |                                   |                            |



| Risk No.                             | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Leave IMRIS Table in Position</b> |   |  |                    |                   |                    |                           |   |                                    |                                   |                            |
| 7.                                   | <p><b>What:</b><br/>The MRI Neurosuite not being fully utilised for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The full MRI Neurosuite being presently utilised for approx. 12 cases per year.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table but does not have an interchangeable Table top.</li> <li>Surgical staff consider that the IMRIS Operating Table is not wide enough (606.5 mm) for general surgery and limited in its use, such as in spinal surgery.</li> <li>The IMRIS ORT 100 Operating Table with the back section removed and the body rotated 180 degrees not allowing</li> </ul> | <ul style="list-style-type: none"> <li>IMRIS claim that the ORT100 operating table was designed to cater for the "vast majority of surgical procedures", however admit that certain specialised procedures, such as spinal surgery, are best performed on an alternate table.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table with a wide range of movements and functionality, but "essentially it is a standard operating table that is MR compatible".</li> <li>The back section of the ORT100 table is radiolucent and therefore</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Rotate the IMRIS ORT 100 Operating Table into the least obstructive position, remove the backrest and cover/protect the table top from liquid ingress and damage.</li> <li>Do not use the Jackson Spinal operating theatre table in this operating theatre.</li> <li>Regulate the use of this operating theatre to general surgical, neurosurgical and other procedures that can be performed on the IMRIS ORT 100 Operating Table.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p>enough room for the extra long Jackson Spinal operating table.</p> <ul style="list-style-type: none"> <li>Surgical staff not satisfied with using the remaining part of the IMRIS Operating Table top for holding instruments and consumables during surgery.</li> <li>This operating theatre is considered by surgical staff as a neurosuite and not for other surgical procedures that the IMRIS Operating Table would facilitate.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Less surgical treatments</li> <li>Loss of income</li> <li>Not meeting surgical KPIs</li> <li>Loss of reputation</li> </ul> | <p>X-ray compatible.</p> <ul style="list-style-type: none"> <li>The ORT100 table has a removable back section and the body rotates 180 degrees, which is useful if an alternate operating table is used alongside.</li> <li>There is an optional table top for use with neonates.</li> <li>The MRI Neurosuite is very large, there appears to be adequate room for an alternative normal sized operating table to be used alongside the ORT100 table.</li> <li>IMRIS reported that other hospitals approach the problem by leaving the IMRIS operating table fixed in situ and wheel in an alternate table and operate it along-side the IMRIS table.</li> </ul> |                    |                   |                    |                           |                 |                                    |                                   |                            |

| Risk No.                         | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------------------------------|---|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 8.                               | <p><b>What:</b><br/>Permanent loss of function for the patient unrelated to the underlying illness.</p> <p><b>Due to:</b><br/>The IMRIS ORT100 Operating Table has a defective locking pin mechanism on the swivel of the base that allows limited free movement of the table top even when locked into position.</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect movement in the operating table.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> | <ul style="list-style-type: none"> <li>Moving the operating table top until it is fixed in position after the locking mechanism is applied.</li> </ul> | Major              | Almost certain    | High               | Yes                       | <ul style="list-style-type: none"> <li>Supplier / manufacturer is "releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock".</li> <li>Supplier / manufacturer to fit new entire locking mechanism.</li> <li>Health Directorate as part of duty of care to notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</li> </ul> | Major                              | Unlikely                          | High                       |
| <b>Other Incidental Findings</b> |   |  |                    |                   |                    |                           |  |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 9.       | <p><b>What:</b><br/>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Unclear responsibility for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>Staff without appropriate training and endorsement by the manufacturer interchanging the IMRIS Operating Table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect operation in the MRI Neurosuite equipment.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Scrutiny by external committees</li> </ul> | Supplier / manufacturer maintained the medical equipment during its warranty period. Various Health Directorate staff perform other maintenance and calibrating functions. | Major              | Almost certain    |                    |                        | <ul style="list-style-type: none"> <li>Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>IMRIS ORT100 Operating Table is an integral part of the medical equipment in the MRI Neurosuite.</li> <li>Technical expertise for medical equipment is with Biomedical Engineering Services, i.e. clinical engineering and medical physics.</li> <li>Appropriate training and endorsement by the manufacturer of the maintenance staff and other staff for the MRI Neurosuite, including the IMRIS ORT100 Operating Table</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|---|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 10.      | <ul style="list-style-type: none"> <li>Financial loss</li> </ul> <p><b>What:</b><br/>Operating theatres at TCH not fitted with appropriate medical equipment contributing to backlog in surgical operations.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Incompatible operating theatres to the requirements of the surgeons / theatre staff.</li> <li>Limited use of operating theatres due to old theatre pendants, theatre lights and communication cables.</li> <li>The MRI Neurosuite is required to be left "Ready To Scan" at the end of each day.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Backlog in surgery cases.</li> <li>No spare operating theatre for shutdown of other theatres to allow replacing the theatre pendants, lights and cabling</li> </ul> | <ul style="list-style-type: none"> <li>The two Jackson Spinal operating tables are presently used in the other operating theatres.</li> <li>Daily operating theatre scheduling with little or no spare capacity.</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>Provide manufacturer manuals for the maintenance and upkeep of the IMRIS ORT100 Operating Table.</li> <li>Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed. Estimated to take 16 working days shutdown for each two operating theatres to do the updating work. It would require 4 (set of 2 theatres) x 16 = 64 working days to complete this previously planned work.</li> <li>Negotiate agreement with other surgical service providers to facilitate surgery during the remediation work, e.g. Royal Darwin Hospital used portable operating theatres installed on-site from the Defence</li> </ul> | Moderate                           | Unlikely                          | Medium                     |



| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 11.      | <p>work; they require updating and making safer.</p> <p><b>What:</b><br/>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Ferrous objects attracted to the magnet.</li> <li>Leaving small metal items or fragments after surgery in the MRI Neurosuite that will be attracted to the magnet when it starts to function, such as pins, screws, metal thread and fragments from implants.</li> <li>Likelihood of occurrence increase if this theatre is used for some other surgical procedures, e.g. implants, orthopaedic.</li> </ul> <p><b>Resulting in:</b></p> |  | Moderate           | Possible          | Medium             |                           | <ul style="list-style-type: none"> <li>Department.<br/>Re-evaluate interchanging the IMRIS Operating Table after the operating theatre pendants have been replaced in all the other theatres.</li> <li>Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this theatre, including the cleaning, technical and clinical staff.</li> <li>Schedule appropriate surgical cases for this theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</li> <li>Conduct a metal sweep with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |



|   |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|
| <b>Risk No.</b>   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Risk Description</b><br>What can happen and how                      | <ul style="list-style-type: none"> <li>• Unclear images.</li> <li>• Injury to staff</li> </ul> |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Current Controls</b><br>What do you already do to mitigate the risk? |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Consequence Rating</b>   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Likelihood Rating</b>  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Current Risk Level</b>   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Acceptability</b><br>Yes / No  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Risk Treatments</b>  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Consequence Rating after Treatment</b>                               |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Likelihood Rating after Treatment</b>                                |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>Risk Level after Treatment</b>                                       |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Baker, Jennie**

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**From:** Baker, Jennie  
**Sent:** Tuesday, 23 August 2011 9:23 AM  
**To:** Scott, Adrian  
**Subject:** FW: IMRIS Operating table - Removal FYI

FYI

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**From:** Kirchner, Horst  
**Sent:** Tuesday, 23 August 2011 7:55 AM  
**To:** Cotterill, James; Baker, Jennie; Geoghegan, Sean; Van Lith, Martin  
**Subject:** RE: IMRIS Operating table - Removal

James, thanks for the update, good to hear it went OK.

cheers

*Horst Kirchner*  
 Business & Infrastructure  
 Strategic Support  
 Bldg. 6, L3, TCH  
 62050363  
 mob. [REDACTED]

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**From:** Cotterill, James  
**Sent:** Tuesday, 23 August 2011 7:54 AM  
**To:** Baker, Jennie; Geoghegan, Sean; Van Lith, Martin; Kirchner, Horst  
**Subject:** IMRIS Operating table - Removal

Hi Martin/Jennie/Sean/Horst

...e removal of the IMRIS table went well and the theatre is now ready for use.  
 We cleaned the floor around the table and checked for ferrous material with the magnetic roller.

[REDACTED] the technician from IMRIS, was there at the time and we asked him a few questions about the table. [REDACTED] is a new employee, he joined IMRIS just 4 weeks ago..so he only had limited product knowledge on the table.

The following information was obtained/observed

1. There is no safety shutoff valve within the table to protect should hydraulic pressure be lost – this is a serious problem!
2. He was aware there was a problem with the locking pins, but he had no hands on experience as yet dealing with the problem
3. He was aware there was a factory recall, of sorts, for the locking pin and that new parts were being manufactured to solve the issue.
4. Michael was able to adjust the locking pins so the table became stable, no movement – however this adjustment seemed to be quite sensitive and could alter over time.

5. I noticed there was a 3-4 second delay in the table responding to table movement requests via the remote control – indicating there is already a reduction in pressure in the hydraulics!
6. I also noticed the hydraulic lines, actuators underneath the table are open, there is no drain/capture device, should a leak occur oil could reach the floor and cause a serious hazard

In light of the above and previous observations I am still of the opinion that this table should not be used again until the locking pin recall has been implemented.

The table hydraulic systems are vulnerable from regular removed/reinstallation, serious clinical repercussions may occur if we continue to removal/reinstall this table.

My advice: When the new locking pin assembly is ready to be installed, IMRIS should reinstall the table back into the theatre, install the new pin and recertify the table.

The table should then be left in place, never to be removed again.

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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Care Excellence Collaboration Integrity

**McClymont, Geoff**

---

**From:** Cotterill, James  
**Sent:** Wednesday, 24 August 2011 7:43 AM  
**To:** Jeff Koffman  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Thank you Jeff, the manuals will stay on a protected hard drive and will not be shared.

Kind regards

James

---

**From:** [REDACTED]  
**Sent:** Wednesday, 24 August 2011 4:29 AM  
**To:** Cotterill, James  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

Here are the ORT100 manuals. Please note that these are proprietary materials and are not for external distribution.

Best Regards,  
[REDACTED]

---

**From:** Cotterill, James [mailto:James.Cotterill@act.gov.au]  
**Sent:** August-21-11 5:17 PM  
**To:** [REDACTED]  
**Subject:** RE: Manufacturing defect IMRIS MRI table

[REDACTED]

Thank you, we just like to have service manuals for all of the assets we have, the question was raised if we had a manual or not when a discussion arose regarding the in house servicing of the table  
If you could send the service manual it would be appreciated.

Regards James

---

**From:** [REDACTED]  
**Sent:** Sunday, 21 August 2011 2:28 PM  
**To:** Cotterill, James  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Resend...bounced back to me.

---

**From:** [REDACTED]  
**Sent:** August-18-11 11:42 PM  
**To:** 'Cotterill, James'  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

Sure its not a problem.... but did something happen with the IMRIS service guys as they should still be coming to fix the table. I realize warranty has expired but we were going to get that resolved when Alan Ringland gets back from leave (we would just backdate the service contract).

For now , all I have on my laptop is the attached. Please let me know if the IMRIS service guys are not coming and I will investigate. If the guys are coming do you still want the service manual

Best Regards,

**From:** Cotterill, James [mailto:James.Cotterill@act.gov.au]  
**Sent:** August-18-11 8:05 PM  
**To:** [REDACTED]  
**Subject:** RE: Manufacturing defect IMRIS MRI table

I was wondering if we could be sent a service manual for the OT100?  
Since our warranty is now null and void it appears we will need to service the table.

Regards

James Cotterill  
Biomedical Engineering  
Canberra Hospital

**From:** [REDACTED]  
**Sent:** Wednesday, 17 August 2011 11:37 AM  
**To:** Cotterill, James  
**Cc:** [REDACTED]  
**Subject:** RE: Manufacturing defect IMRIS MRI table

Hi James,

[REDACTED] who are currently in Melbourne (on the RCH install) will be contacting you shortly to arrange a time to come.

Best Regards,



M. 204 291 6707 (Canada)  
M. 03 9005 6799 (Australia)  
M. 70 7847 7036 (South Korea)  
M. 852 8199 9245 (Hong Kong)  
E. [REDACTED]  
[www.imris.com](http://www.imris.com)

**From:** Cotterill, James [mailto:James.Cotterill@act.gov.au]  
**Sent:** August-16-11 8:17 PM  
**To:** [REDACTED]  
**Subject:** Manufacturing defect IMRIS MRI table

To: [REDACTED]  
IMRIS Australia

[REDACTED]


You may recall we were in contact a few weeks ago regarding the removal of the IMRIS table at the Canberra Hospital.  
Now we have another issue... upon installation of the table last week we noticed the table itself was unstable. The problem was found to be related to the manual locking mechanism which allows the table be unlocked and rotated up to 180 degrees.  
There appears to be a manufacturing defect in this locking mechanism which allows too much free play..as a consequence the table can move sideways.  
As you can imagine this poses a serious risk to patient safety, accordingly we, Biomedical Engineering are advising our staff not to use the table until it has been repaired.

I was made aware that IMRIS was also aware of this issue and is producing a in the field upgrade kit. Could you please let me know when our table could be fitted with the upgrade.

Many thanks

Regards

**James Cotterill**  
Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)

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**McClymont, Geoff**

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**From:** Cotterill, James  
**Sent:** Wednesday, 24 August 2011 7:52 AM  
**To:** Van Lith, Martin; Ringland, Alan  
**Subject:** IMRIS Service manuals

Hi Martin/Al

Just letting you know we now have the IMRIS service manuals on the 'G' drive.  
IMRIS have stressed that these manuals are for TCH internal use only

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**Baker, Jennie**

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**From:** Reid, Barbara  
**Sent:** Wednesday, 24 August 2011 3:02 PM  
**To:** JasonSmith, Rhona; Cotterill, James; Baker, Jennie; Geoghegan, Sean; Van Lith, Martin; Kirchner, Horst  
**Cc:** Lang, Kellie  
**Subject:** RE: IMRIS Operating table - Removal

Hi Rhona

I was notified on Friday of the 3-4 second delay in the table responding which it was explained that been there since day one essentially. What I don't understand is why this has not been addressed before now or has it and no-one has let me know.

Barb

**Barbara Reid**  
Executive Director  
Division of Surgery & Oral Health

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**From:** JasonSmith, Rhona  
**Sent:** Wednesday, 24 August 2011 2:53 PM  
**To:** Cotterill, James; Baker, Jennie; Geoghegan, Sean; Van Lith, Martin; Kirchner, Horst  
**Cc:** Reid, Barbara  
**Subject:** RE: IMRIS Operating table - Removal

Hi Folks

Please note regarding dot point 5. There has always been a 3 -4 second delay in the table responding since it was first installed. I think the hypothesis may need to be checked with iMRIS as this may be how the table operates or, it was faulty from the beginning. I am assuming this is what iMRIS expects as they tested the unit before handing it over.

Regards  
Rhona

Rhona JasonSmith  
Assistant Director of Nursing Perioperative Services  
The Canberra Hospital  
ph (02) 62443051  
fx (020 6244 3348

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**From:** Cotterill, James  
**Sent:** Tuesday, 23 August 2011 7:54 AM  
**To:** Baker, Jennie; Geoghegan, Sean; Van Lith, Martin; Kirchner, Horst  
**Subject:** ==printed== IMRIS Operating table - Removal

Hi Martin/Jennie/Sean/Horst

The removal of the IMRIS table went well and the theatre is now ready for use.  
We cleaned the floor around the table and checked for ferrous material with the magnetic roller.

Michael the technician from IMRIS, was there at the time and we asked him a few questions about the table. Michael is a new employee, he joined IMRIS just 4 weeks ago..so he only had limited product knowledge on the table.

The following information was obtained/observed

1. There is no safety shutoff valve within the table to protect should hydraulic pressure be lost – this is a serious problem!
2. He was aware there was a problem with the locking pins, but he had no hands on experience as yet dealing with the problem
3. He was aware there was a factory recall, of sorts, for the locking pin and that new parts were being manufactured to solve the issue.
4. Michael was able to adjust the locking pins so the table became stable, no movement – however this adjustment seemed to be quite sensitive and could alter over time.
5. I noticed there was a 3-4 second delay in the table responding to table movement requests via the remote control – indicating there is already a reduction in pressure in the hydraulics!
6. I also noticed the hydraulic lines, actuators underneath the table are open, there is no drain/capture device, should a leak occur oil could reach the floor and cause a serious hazard

In light of the above and previous observations I am still of the opinion that this table should not be used again until the locking pin recall has been implemented.

The table hydraulic systems are vulnerable from regular removed/reinstallation, serious clinical repercussions may occur if we continue to removal/reinstall this table.

My advice: When the new locking pin assembly is ready to be installed, IMRIS should reinstall the table back into the theatre, install the new pin and recertify the table.

The table should then be left in place, never to be removed again.

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**Baker, Jennie**

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**From:** Van Lith, Martin  
**Sent:** Thursday, 25 August 2011 8:38 AM  
**To:** Cotterill, James  
**Cc:** Baker, Jennie  
**Subject:** RE: IMRIS Operating table - Removal

Hello James

Thank you for the update.

I suggest that it would be good to follow up these technical matters with IMRIS, while the Table is out of use, it is an opportunity to do some work on it if necessary. I would think that the delay in response to the remote control for controlling the Table is a problem waiting to happen, unless you are accustomed to it.

I contacted [REDACTED] from IMRIS today by Email for more information on a removable Table or interchangeable table tops (as requested by Barbara Reid and Adrian Scott).

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and client-focused services*

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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**From:** Cotterill, James  
**Sent:** Tuesday, 23 August 2011 7:54 AM  
**To:** Baker, Jennie; Geoghegan, Sean; Van Lith, Martin; Kirchner, Horst  
**Subject:** IMRIS Operating table - Removal

Hi Martin/Jennie/Sean/Horst

The removal of the IMRIS table went well and the theatre is now ready for use.  
We cleaned the floor around the table and checked for ferrous material with the magnetic roller.

Michael the technician from IMRIS, was there at the time and we asked him a few questions about the table. Michael is a new employee, he joined IMRIS just 4 weeks ago..so he only had limited product knowledge on the table.

The following information was obtained/observed

1. There is no safety shutoff valve within the table to protect should hydraulic pressure be lost – this is a serious problem!
2. He was aware there was a problem with the locking pins, but he had no hands on experience as yet dealing with the problem
3. He was aware there was a factory recall, of sorts, for the locking pin and that new parts were being manufactured to solve the issue.
4. Michael was able to adjust the locking pins so the table became stable, no movement – however this adjustment seemed to be quite sensitive and could alter over time.
5. I noticed there was a 3-4 second delay in the table responding to table movement requests via the remote control – indicating there is already a reduction in pressure in the hydraulics!

6. I also noticed the hydraulic lines, actuators underneath the table are open, there is no drain/capture device, should a leak occur oil could reach the floor and cause a serious hazard

In light of the above and previous observations I am still of the opinion that this table should not be used again until the locking pin recall has been implemented.

The table hydraulic systems are vulnerable from regular removed/reinstallation, serious clinical repercussions may occur if we continue to removal/reinstall this table.

My advice: When the new locking pin assembly is ready to be installed, IMRIS should reinstall the table back into the theatre, install the new pin and recertify the table.

The table should then be left in place, never to be removed again.

Regards

**James Cotterill**

Biomedical Engineering Technician | Biomedical Engineering Department  
Phone: 6244 3831 | Fax: 6244 3819 | Email: [james.cotterill@act.gov.au](mailto:james.cotterill@act.gov.au)



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**McClymont, Geoff**

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**From:** Geoghegan, Sean  
**Sent:** Monday, 26 March 2012 4:39 PM  
**To:** McClymont, Geoff  
**Subject:** iMRI FOI - FW: IMRIS Operating Room Table  
**Attachments:** Review report 220811.docx; Risk\_Plan\_20110818.docx

---

**From:** Geoghegan, Sean  
**Sent:** Friday, 26 August 2011 8:05 AM  
**To:** Amponin, Gretchen  
**Subject:** FW: IMRIS Operating Room Table

Hi Gretchen,

Would you please print these and add them to our MRI file.

Cheers,

Sean

**Sean Geoghegan**

Chief Medical Physicist Medical Physics and Medical Technology Systems

Phone: 6244 2256 | Mobile: [REDACTED] | Fax: 6244 3819 | Email: [sean.geoghegan@act.gov.au](mailto:sean.geoghegan@act.gov.au)



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**From:** Van Lith, Martin  
**Sent:** Thursday, 25 August 2011 3:48 PM  
**To:** Baker, Jennie; Thorburn, Phillip; Geoghegan, Sean; JasonSmith, Rhona; Kirchner, Horst; Cotterill, James; Swain, Rob  
**Subject:** FW: IMRIS Operating Room Table

Hello

Attached is the Final report of the review to develop a risk management plan and identify key risks associated with the frequent interchange (removal and re-installation) of the IMRIS Operating Table in the MRI Neurosuite at TCH following various concerns associated with interchanging of the Table.

The following is a brief summary of action taken so far on the report recommendations:

1. The E/Ds of Surgery & Oral Health Division and Business & Infrastructure Branch met on 22 August 2011 to discuss the review.

In the meantime the pendants in Operating Theatre 7 have become loose and are no longer safely fixed due to the fixing brackets and bolts coming away. The workplace safety hazards make the operating theatre unsafe to use.

The Executive Director of Surgery & Oral Health Division has determined that the IMRIS Operating Table be removed until further notice so that the Neurosuite can be used for other surgical procedures. Moveable operating tables from the other operating theatres will be used in the Neurosuite.

The IMRIS service technician assisted Biomedical Engineering Services staff to remove the IMRIS Table on Monday evening 22 August 2011.

Further discussion are being held with IMRIS for designing a removable Operating Table suitable for use in the MRI Neurosuite and/or an interchangeable Operating Table top.



- 2. IMRIS has designed and agreed to fit a new locking mechanism and notified the Therapeutic Goods Administration (TGA) of the problem with the Table. Biomedical Engineering Services has also notified TGA of the problem.
- 3. The E/D Business & Infrastructure Branch has advised Biomedical Engineering Services for the maintenance and upkeep of the medical equipment in the MRI Neurosuite. Service Manuals have been obtained from the manufacturer and training is being considered.

Many thanks for the hard work and information that you provided in putting this report and risk management plan together.

Kind regards

**Martin Van Lith**  
 Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and client-focused services*  
 Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
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**From:** Van Lith, Martin  
**Sent:** Thursday, 25 August 2011 3:02 PM  
**To:** Reid, Barbara; Scott, Adrian  
**Cc:** Staniforth, Robyn  
**Subject:** IMRIS Operating Room Table

Hello Barbara and Adrian

Attached is the Final report of the review to develop a risk management plan and identify key risks associated with the frequent interchange (removal and re-installation) of the IMRIS Operating Table in the MRI Neurosuite at TCH following various concerns associated with interchanging of the Table. The review considered the risks for interchanging the IMRIS Operating Table and also for leaving it in position. The review process uncovered other important and closely related risks. The identified key risks were analysed, current controls identified, assessed and risk treatments proposed to lower the risk levels. Recommendations were based on the proposed risk treatments for interchanging the IMRIS Operating Table and also for leaving it in position.

The supplier and manufacturer, Intra-Operative Magnetic Resonance Imaging System (IMRIS) Inc. based in Canada, has been contacted for more information on the use of the IMRIS Operating Table other than for neurosurgery. The [redacted] would like to know what other purpose we wish to use the Table, e.g. is it just for a longer table or a table that bends.

In addition, I have asked [redacted] to provide us with information on IMRIS designing and manufacturing a removable Operating Table and to also consider the option of designing and using interchangeable Table tops.

[redacted] can be contacted by telephone 03 9005 6799, even though he may be working in Canada or elsewhere. (8.00am in Canberra is 5.00pm in Winnipeg on the day before, Canada). His Email address is [redacted]

Will keep you informed as further information comes to hand

Kind regards

**Martin Van Lith**  
 Coordinator, Accreditation and Risk Management, Systems & Reporting  
*Business and Infrastructure – committed to timely, responsive and*

***client-focused services***

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>

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**Business & Infrastructure Branch**  
with support from  
**Surgery and Oral Health Division**  
&  
**Quality and Safety Unit**

**Review**

**Interchange of IMRIS Operating Table in the MRI  
Neurosuite at TCH**

**Final Report**

22 August 2011

## Executive Summary

The review set out to develop a risk management plan and identify key risks associated with the frequent interchange (removal and re-installation) of the IMRIS Operating Table in the MRI Neurosuite at TCH following various concerns associated with interchanging of the Table.

The IMRIS Operating Table has been interchanged to make way for other operating theatre tables so that the operating theatre can be used for other surgical procedures.

The IMRIS Operating Table was supplied and fixed to the floor as part of the installation of the MRI Neurosuite during 2010. The supplier and manufacturer is Intra-Operative Magnetic Resonance Imaging System (IMRIS) Inc. based in Canada.

The review considered the risks for interchanging the IMRIS Operating Table and also for leaving it in position. The review process uncovered other important and closely related risks.

The identified key risks were analysed, current controls identified, assessed and risk treatments proposed to lower the risk levels.

Recommendations were based on the proposed risk treatments for interchanging the IMRIS Operating Table and also for leaving it in position.

### 1. Report Owner

The review was initiated and the report is owned by the Business & Infrastructure Branch Executive Director, currently acting in this position is Mr Adrian Scott.

The review team included:

Martin Van Lith - Coordinator, Accreditation & Risk Management, Business & Infrastructure Branch.

Phil Thorburn – Biomedical Engineer, Redevelopment Unit, Service & Capital Planning

Rhona JasonSmith - Assistant Director of Nursing Perioperative Services

Horst Kirchner - Project Manager, Strategic Asset Management & Accommodation

James Cotterill - Biomedical Engineering Technician, Clinical Engineering

Sean Geoghegan - Chief Medical Physicist, Medical Physics and Medical Technology Systems

Rob Swain - Assistant Director, Workplace Safety, Quality & Safety Unit

### 2. Review Objectives and Scope

The objectives of the review team were to:

- Establish the facts with the interchange of the IMRIS Operating Room Table using Risk Analysis
- Provide a report of the review findings and formulate recommendations
- Look for system gaps and opportunities for improvement

The scope of the review included the interchange of the IMRIS Operating Room Table in the MRI Neurosuite at TCH.

### 3. Review Process

The review process consisted of:

- A documentation review including related Emails and Product Manuals;
- Site visits and demonstration of the re-installation;
- Interviews with key stakeholders;
- Analysis of findings utilising risk analysis;
- Reporting of the findings and recommendations; and
- A risk analysis to support the report (Attachment A).

A telephone discussion was held with Dr John Fuller, Head of Neurosurgery, on 17 August 2011. He stated that the MRI Neurosuite should be used more often as an operating theatre and not wasted. He also stated that as a surgeon he considered that the IMRIS Operating Table was not suitable for other surgery. His opinion was that the operating theatre should be used and that it required the IMRIS Operating Table be moved to make way for other operating theatre tables.

### 4. Summary of Key Risks and Recommendations

The review found that most interviewed stakeholders were concerned over the governance, management and safety associated with the frequent interchange (removal and re-installation) of IMRIS Operating Table in the MRI Neurosuite at TCH.

The Risk Management Plan in Attachment A contains the key risks that fell into the following main categories:

- Clinical
- People
- Property and Services
- Financial
- Business Process and Systems
- Reputation

## Key Risks and Recommendations

| Risks   | Recommendation   |
|---|--|
| <ul style="list-style-type: none"> <li>• The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</li> <li>• All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS Operating Table, has been moved from the manufacture and installer to the Health Directorate.</li> <li>• Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</li> <li>• Interchanging the IMRIS Operating Table causes premature 'wear and tear', as well increases the chance for error during each installation.</li> <li>• Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</li> </ul> | <p>1.1 Do not interchange the IMRIS ORT100 Operating Table in the MRI Neurosuite.</p> <p>OR</p> <p>1.2 If the IMRIS ORT100 Operating Table is to be interchanged then implement the risk treatments outlined in the Risk Management Plan</p> <p>1.3 Investigate with IMRIS designing a removable Operating Table suitable for use in the MRI Neurosuite and/or an interchangeable Operating Table top.</p> |
| <p>Permanent loss of function for the patient unrelated to the underlying illness.</p>  | <p style="text-align: center;"><b>Recommendation</b></p> <p>2.1 Supplier / manufacturer to fit a new entire locking mechanism to the IMRIS ORT100 Operating Table.</p> <p>2.2 Health Directorate notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</p>   |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p>   | <p>3.1 Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</p> <p>3.2 Appropriate training and endorsement by the manufacturer for the maintenance staff &amp; other staff for the IMRIS ORT100 Operating Table.</p>  |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p>  | <p>4.0 Modify operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding existing theatre light.</p>  |
| <b>Risk</b>   | <b>Recommendation</b>  |
| <p>The MRI Neurosuite not being fully utilised for surgery.</p>   | <p>5.1 Utilise the IMRIS ORT 100 Operating Table into the least obstructive position when using other operating theatre tables,<br/>AND / OR</p> <p>5.2 Regulate the use of the MRI Neurosuite to surgical procedures that can be performed on the IMRIS ORT 100 Operating Table.</p>  |



| Risk  | Recommendation   |
|---|--|
| <p>Operating theatres at TCH not fitted with appropriate medical equipment contributing to backlog in surgical operations.</p>                      | <p>6.0 Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed.</p>   |
| Risk  | Recommendation   |
| <p>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> | <p>7.1 Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this operating theatre, including the cleaning, technical and clinical staff.</p> <p>7.2 Schedule appropriate surgical cases for this operating theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</p> <p>7.3 Conduct a metal sweep of the operating theatre with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</p> |

## 5. Conclusion

The risk management plan identified key risks associated with the frequent interchange (removal and re-installation) and also for leaving fixed the IMRIS Operating Table in the MRI Neurosuite at TCH. The process also highlighted other important and closely related risks.

The risk management planning process identified three extreme level, six high level and two medium level risks.

Expedient attention is urged to address the following three extreme level risks.

1. It is recommended that the IMRIS ORT100 Operating Table not be interchanged. The review identified an extreme risk associated with interchanging the IMRIS ORT100 Operating Table from the adverse effect on the correct and accurate function of the table, premature 'wear and tear', increased chance for error during installation, increased liability and possibility to increased litigation exposure, as well as staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate.

If the IMRIS ORT100 Operating Table is to be interchanged then it is recommended that the risk treatments outlined in the Risk Management Plan under Risk Nos. 1, 2, 3 4 and 5 be implemented.

2. It is recommended that the supplier/manufacturer of the IMRIS ORT100 Operating Table fits a new entire locking mechanism and that the Therapeutic Goods Administration (TGA) be notified of the problem with the Table. Limited free movement of the Table top presents an extreme risk from permanent loss of function for the patient unrelated to the underlying illness.
3. It is also recommended that responsibility and appropriate resources be allocated, including ongoing costs, for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table. Appropriate training is required and endorsement by the manufacturer for the maintenance staff & other staff for the IMRIS ORT100 Operating Table.

Recommendations 4.0, 5.1, 5.2, 6.0, 7.1, 7.2 and 7.3 listed in the Table above also apply and are presented for follow-up and action to lower the other high and medium risks identified during the review.



# RISK MANAGEMENT PLAN

**Title (Project / Activity / Program):** Interchange of IMRIS Operating Table in the MRI Neurosuite at TCH **File No:** .....

**Objective / Background:** Developing a risk management plan and identifying any risks associated with the frequent removal and re-installation of IMRIS Operating Room Table in the MRI Neurosuite at TCH

**Prepared by:** Martin Van Lith, Phil Thorburn, Sean Geoghegan, Rhona JasonSmith, Horst Kirchner, James Cotterill, Rob Swain **Date:** 22 August 2011  
**Reviewed by:** Adrian Scott, Barbara Reid **Date:** 22 August 2011

| Risk No.                       | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Interchange IMRIS Table</b> |   |  |                    |                   |                    |                           |   |                                    |                                   |                            |
| 1                              | <p><b>What:</b><br/>The process of interchanging the IMRIS ORT100 Operating Table has adverse effect on the correct and accurate function of the table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>There are many mechanical parts, such as screws, at the base plate involved in the interchange of the IMRIS</li> </ul> | <ul style="list-style-type: none"> <li>A dedicated toolkit and parts list has been made for the interchange.</li> <li>A written procedure containing illustrative photographs has been drafted and tested.</li> <li>Workplace safety analysis has been made and issues addressed</li> <li>IMRIS has been consulted throughout the project.</li> <li>Cleaning operating procedure developed and tested.</li> <li>A purpose built lifting</li> </ul> | Major              | Almost certain    | Extra High         |                           | <ul style="list-style-type: none"> <li>Develop responsibility and training of staff for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Use a checklist for the removal and also re-installation of the IMRIS ORT100 Operating Table.</li> <li>Checklist to be used by the installation staff and a separate list by the spotter. Verify lists and sign off at the end of installation.</li> <li>Use one independent person as a spotter during</li> </ul> | Major                              | Possible                          | High                       |

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| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk?                                    | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|---|--------------------|-------------------|--------------------|------------------------|--|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>operating table.</li> <li>Responsibility and training of staff for the removal and re-installation not clear.</li> <li>The two hydraulic lines and connectors in the floor are thin walled solid metal tubing AND are flexed each time the table is moved. They are held in a flexed position under the cover plate. The stainless steel tubing will caseharden over time in the flexed (stressed) position and is almost certain to crack. The hydraulic lines are also more vulnerable to damage if the table is moved on a regular basis.</li> <li>The hydraulic system is at very high pressure and the connector fittings are not designed for a large number disconnections and reconnections to be made and is almost certain to fail after a finite number of installations.</li> <li>Every time the table is moved a small amount of oil leaks out and the possibility can arise where air bubbles may become trapped within the lines. The trapped air can then travel throughout the hydraulic circuit.</li> </ul> | <p>device has been procured to lift, move and support the table during storage when not in use.</p> |                    |                   |                    |                        | <ul style="list-style-type: none"> <li>removal and re-installation.</li> <li>Independent check each time of the re-installation of the IMRIS ORT100 Operating Table, e.g. mechanical, electrical, alignment, functions of the theatre table, verification of two checklists.</li> <li>Review the mechanical loading capability of the side rails of the IMRIS ORT 100 Operating Table to support its own weight indefinitely and provide a supporting base to the table when in storage if required.</li> <li>Re-engineer the base of the table to allow reliable reconnection of the hydraulic system and increased durability of the connecting tubes.</li> <li>Re-engineer the covers and underlying screw holes to allow reliable refitting of the covers without the generation of fillings.</li> <li>Schedule the removal and</li> </ul> |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>Electrical wire connections need to be applied correctly.</li> <li>Potential for dirt and metal filings to remain in the operating theatre after the interchange</li> <li>The concrete supporting the base of the table is cracked by the repeated application and removal of loading stress making the base unstable.</li> <li>The screw holes are not aligned with the holes on the cover plates leading to the screw holes needing to be tapped or the cover plates modified (this has a current frequency of about 1 every 3 to 4 reinstalls).</li> <li>The side rails, used to support the table on the table lift when the table is not in use and in storage, fail due to the continual load being placed on the rails.</li> <li>The time pressure to complete the re-installation of the table leading to errors in reassembly of components of the table.</li> </ul> |  |                    |                   |                    |                           | reinstallation of the table allowing at least two hours for the process prior to any cleaning or preparation of the theatre for a clinical case. |                                    |                                   |                            |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect movement in the operating table.</li> <li>Production of metallic filings and the inadvertent deposition of other mobile magnetisable objects which interfere with the MRI magnetic field or act as projectiles when the magnet is moved into the operating theatre.</li> <li>Damage to the table.</li> <li>Injury to a bystander (staff or patient).</li> <li>If the hydraulic lines did fail and there is a sudden loss of hydraulic pressure the effect 'could' be unwanted movement of the table bed and that 'could' create a life threatening situation.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Permanent loss of function for the patient unrelated to the underlying illness.</li> <li>Repairs to the hydraulic lines would be an expensive and lengthy process.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> |  |                    |                   |                    |                           |                 |                                    |                                   |                            |



| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 2        | <p><b>What:</b><br/>All liability for using the MRI equipment in the MRI Neurosuite, including the IMRIS operating table, has been moved from the manufacture and installer to the Health Directorate.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The IMRIS Operating Table is part of the MRI machine as an integrated and calibrated system in the Neurosuite.</li> <li>The IMRIS Operating Table has been designed to be fixed / bolted into position and not moved; moving the table takes it outside the manufacturers design parameters.</li> <li>Health Directorate modifying the IMRIS operating table.</li> <li>The purpose of the IMRIS operating table has been changed from fixed equipment to interchangeable.</li> <li>The local IMRIS representative does <i>not</i> support the interchange of the IMRIS operating table and warns against such action.</li> <li>Removing the IMRIS Operating Table has voided the</li> </ul> | Not adequately addressed   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>IMRIS re-install and certify the ORT100 operating table may reduce this liability</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how  | Current Controls<br>What do you already do to mitigate the risk? | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|--|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 3        | <p>manufacturer's warranty and introduced the possibility for a range of risk and liabilities</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Legal liability</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> <p><b>What:</b><br/>Litigation from a complication associated with a clinical case following the interchanging of the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Supplier knows that Health Directorate is interchanging the IMRIS Operating Table and advised against it.</li> <li>• Health Directorate have chosen to use the IMRIS Operating Table outside its design parameter.</li> <li>• Removing the IMRIS Operating Table has voided the manufacturer's warranty and introduced the possibility for a range of risk and liabilities</li> </ul> | <ul style="list-style-type: none"> <li>▪</li> </ul>              | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>▪ Seek legal opinion.</li> </ul> | Major                              | Possible                          | High                       |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 4        | <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Legal liability</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> <li>Reputation loss</li> </ul> <p><b>What:</b><br/>Interchanging the IMRIS operating table causes premature 'wear and tear', as well as increases the chance for error during each installation.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Written procedure for interchanging the IMRIS operating table not being followed.</li> <li>Moving the operating table on a regular basis increases wear and tear on the connecting parts.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Extra costs</li> <li>Interference with theatre booking schedule</li> </ul> | <ul style="list-style-type: none"> <li>Written operating procedure</li> <li>Two people installing and one person observing.</li> <li>Final check and signoff by an independent person following checking the reinstallation.</li> <li>Written procedures for cleaning</li> <li>Magnet roller check for metals</li> </ul> | Moderate           | Possible          | Medium             |                           | <ul style="list-style-type: none"> <li>Investigate with IMRIS designing a removable Operating Table suitable for use in the MRI Neurosuite and/or an interchangeable Operating Table top.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?  | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments  | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|---|--------------------|-------------------|--------------------|---------------------------|--|------------------------------------|-----------------------------------|----------------------------|
| 5        | <p><b>What:</b><br/>Staff or patient on an operating table being injured from unexpectedly coming in contact with the metal floor plate covering the base for the IMRIS Operating Table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• Metal cover plate is a trip hazard to staff and mobile equipment in the theatre.</li> <li>• The 'hump' in the metal cover plate presents a hazard if the operating table is moved with a patient.</li> <li>• Busy work environment</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Damage to staff or patients.</li> <li>• Costs</li> </ul> | <ul style="list-style-type: none"> <li>• Workplace safety assessment has been conducted with staff from Workplace Safety and with operating theatre staff.</li> <li>• An operating theatre table to be located over the metal cover plate during use of theatre.</li> </ul> | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Ensure that the metal cover plate has an operating theatre table or other large equipment located over it at all times and does not present a trip hazard.</li> </ul> | Major                              | Unlikely                          | High                       |
| 6        | <p><b>What:</b><br/>Present lighting pendants in the Neurosuite will not effectively cover the whole operating site for a Jackson Spinal operating theatre table.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>• The configuration and location of the theatre lights does not</li> </ul>   |   | Major              | Possible          | High               |                           | <ul style="list-style-type: none"> <li>• Modifying operating theatre light for the MRI Neurosuite, e.g. extending the arm on the pendant holding exiting theatre light.</li> </ul>                             | Major                              | Rare                              | Medium                     |

|                 |  |   |                           |                          |                           |                                  |                        |   |  |                                   |
|-----------------|--|---|---------------------------|--------------------------|---------------------------|----------------------------------|------------------------|---|--|-----------------------------------|
| <b>Risk No.</b> | <b>Risk Description</b><br>What can happen and how   | <b>Current Controls</b><br>What do you already do to mitigate the risk? | <b>Consequence Rating</b> | <b>Likelihood Rating</b> | <b>Current Risk Level</b> | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b> | <b>Consequence Rating after Treatment</b> | <b>Likelihood Rating after Treatment</b> | <b>Risk Level after Treatment</b> |
|                 | <p>provide as effective lighting of the surgical sites when used outside the allocated area for the fixed IMRIS Operating Table.</p> <ul style="list-style-type: none"> <li>The Jackson Spinal operating theatre table is longer than a normal operating table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Inadequate lighting of the surgical site.</li> <li>Injury to patient</li> <li>Modification of the operating theatre light required for the MRI Neurosuite.</li> <li>Extra costs</li> </ul> |   |                           |                          |                           |                                  |                        |   |  |                                   |

| Risk No.                             | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|--------------------------------------|---|--|--------------------|-------------------|--------------------|------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| <b>Leave IMRIS Table in Position</b> |   |  |                    |                   |                    |                        |   |                                    |                                   |                            |
| 7.                                   | <p><b>What:</b><br/>The MRI Neurosuite not being fully utilised for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>The full MRI Neurosuite being presently utilised for approx. 12 cases per year.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table but does not have an interchangeable Table top.</li> <li>Surgical staff consider that the IMRIS Operating Table is not wide enough (606.5 mm) for general surgery and limited in its use, such as in spinal surgery.</li> <li>The IMRIS ORT 100 Operating Table with the back section removed and the body rotated 180 degrees not allowing enough room for the extra long Jackson Spinal operating table.</li> <li>Surgical staff not satisfied with using the remaining part of the IMRIS Operating Table top for holding instruments and consumables during surgery.</li> </ul> | <ul style="list-style-type: none"> <li>IMRIS claim that the ORT100 operating table was designed to cater for the "vast majority of surgical procedures", however admit that certain specialised procedures, such as spinal surgery, are best performed on an alternate table.</li> <li>The IMRIS ORT 100 Operating Table is a fully functional operating table with a wide range of movements and functionality, but "essentially it is a standard operating table that is MR compatible".</li> <li>The back section of the ORT100 table is radiolucent and therefore X-ray compatible.</li> <li>The ORT100 table has a removable back section and the body rotates 180 degrees, which is useful if an alternate operating table is used alongside.</li> <li>There is an optional table</li> </ul> | Major              | Possible          | High               |                        | <ul style="list-style-type: none"> <li>Rotate the IMRIS ORT 100 Operating Table into the least obstructive position, remove the backrest and cover/protect the table top from liquid ingress and damage.</li> <li>Do not use the Jackson Spinal operating theatre table in this operating theatre.</li> <li>Regulate the use of this operating theatre to general surgical, neurosurgical and other procedures that can be performed on the IMRIS ORT 100 Operating Table.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |



| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|-----------------|------------------------------------|-----------------------------------|----------------------------|
|          | <ul style="list-style-type: none"> <li>This operating theatre is considered by surgical staff as a neurosuite and not for other surgical procedures that the IMRIS Operating Table would facilitate.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Less surgical treatments</li> <li>Loss of income</li> <li>Not meeting surgical KPIs</li> <li>Loss of reputation</li> </ul> | <ul style="list-style-type: none"> <li>top for use with neonates.</li> <li>The MRI Neurosuite is very large, there appears to be adequate room for an alternative normal sized operating table to be used alongside the ORT100 table.</li> <li>IMRIS reported that other hospitals approach the problem by leaving the IMRIS operating table fixed in situ and wheel in an alternate table and operate it along-side the IMRIS table.</li> </ul> |                    |                   |                    |                           |                 |                                    |                                   |                            |

Other Incidental Findings

|                 |   |  |                           |                          |                           |                                  |  |   |  |                                   |
|-----------------|---|--|---------------------------|--------------------------|---------------------------|----------------------------------|--|---|--|-----------------------------------|
| <b>Risk No.</b> | <b>Risk Description</b><br>What can happen and how  | <b>Current Controls</b><br>What do you already do to mitigate the risk?  | <b>Consequence Rating</b> | <b>Likelihood Rating</b> | <b>Current Risk Level</b> | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b>   | <b>Consequence Rating after Treatment</b> | <b>Likelihood Rating after Treatment</b> | <b>Risk Level after Treatment</b> |
| 8.              | <p><b>What:</b><br/>Permanent loss of function for the patient unrelated to the underlying illness.</p> <p><b>Due to:</b><br/>The IMRIS ORT100 Operating Table has a defective locking pin mechanism on the swivel of the base that allows limited free movement of the table top even when locked into position.</p> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>• Unwanted / incorrect movement in the operating table.</li> <li>• Incorrect diagnosis</li> <li>• Error in surgery of the patient.</li> <li>• Scrutiny by external committees</li> <li>• Financial loss</li> </ul> | <ul style="list-style-type: none"> <li>• Moving the operating table top until it is fixed in position after the locking mechanism is applied.</li> </ul> | Major                     | Almost certain           | Existing                  |                                  | <ul style="list-style-type: none"> <li>• Supplier / manufacturer is "releasing a Field Change Order to replace the entire locking mechanism for that table with a new design as we have found that it goes out of adjustment too easily and is too difficult to lock".</li> <li>• Supplier / manufacturer to fit new entire locking mechanism.</li> <li>• Health Directorate as part of duty of care to notify Therapeutic goods Administration (TGA) of the problem with the IMRIS ORT100 Operating Table.</li> </ul> | Major                                     | Unlikely                                 | High                              |

| Risk No. | Risk Description<br>What can happen and how   | Current Controls<br>What do you already do to mitigate the risk?   | Consequence Rating | Likelihood Rating | Current Risk Level | Acceptability<br>Yes / No | Risk Treatments   | Consequence Rating after Treatment | Likelihood Rating after Treatment | Risk Level after Treatment |
|----------|---|--|--------------------|-------------------|--------------------|---------------------------|---|------------------------------------|-----------------------------------|----------------------------|
| 9.       | <p><b>What:</b><br/>Medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table not available for surgery.</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Unclear responsibility for the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>Staff without appropriate training and endorsement by the manufacturer interchanging the IMRIS Operating Table.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unwanted / incorrect operation in the MRI Neurosuite equipment.</li> <li>Incorrect diagnosis</li> <li>Error in surgery of the patient.</li> <li>Scrutiny by external committees</li> <li>Financial loss</li> </ul> | Supplier / manufacturer maintained the medical equipment during its warranty period. Various Health Directorate staff perform other maintenance and calibrating functions. | Major              | Almost certain    | Extreme            |                           | <ul style="list-style-type: none"> <li>Clarify responsibility and appropriately resource, including ongoing costs, the maintenance and upkeep of the medical equipment in the MRI Neurosuite, including the IMRIS ORT100 Operating Table.</li> <li>IMRIS ORT100 Operating Table is an integral part of the medical equipment in the MRI Neurosuite.</li> <li>Technical expertise for medical equipment is with Biomedical Engineering Services, i.e. clinical engineering and medical physics.</li> <li>Appropriate training and endorsement by the manufacturer of the maintenance staff and other staff for the MRI Neurosuite, including the IMRIS ORT100 Operating Table</li> <li>Provide manufacturer manuals for the maintenance and upkeep of the IMRIS ORT100 Operating Table.</li> </ul> | Moderate                           | Unlikely                          | Medium                     |

|                        |  |  |                                    |                                      |                                   |                                  |  |   |  |   |
|------------------------|--|--|------------------------------------|--------------------------------------|-----------------------------------|----------------------------------|--|---|--|---|
| <b>Risk No.</b><br>10. | <b>Risk Description</b><br>What can happen and how<br><br><b>What:</b><br>Operating theatres at TCH not fitted with appropriate medical equipment contributing to backlog in surgical operations.<br><br><b>Due to:</b> <ul style="list-style-type: none"> <li>• Incompatible operating theatres to the requirements of the surgeons / theatre staff.</li> <li>• Limited use of operating theatres due to old theatre pendants, theatre lights and communication cables.</li> <li>• The MRI Neurosuite is required to be left "Ready To Scan" at the end of each day.</li> </ul> <b>Resulting in:</b> <ul style="list-style-type: none"> <li>• Backlog in surgery cases.</li> <li>• No spare operating theatre for shutdown of other theatres to allow replacing the theatre pendants, lights and cabling work; they require updating and making safer.</li> </ul> | <b>Current Controls</b><br>What do you already do to mitigate the risk?<br><br><ul style="list-style-type: none"> <li>• The two Jackson Spinal operating tables are presently used in the other operating theatres.</li> <li>• Daily operating theatre scheduling with little or no spare capacity.</li> </ul> | <b>Consequence Rating</b><br>Major | <b>Likelihood Rating</b><br>Possible | <b>Current Risk Level</b><br>High | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b><br><br><ul style="list-style-type: none"> <li>• Schedule the work for the upgrading of the other eight operating theatres with improved theatre pendants, lights and cabling work, as previously planned and partially completed. Estimated to take 16 working days shutdown for each two operating theatres to do the updating work. It would require 4 (set of 2 theatres) x 16 = 64 working days to complete this previously planned work.</li> <li>• Negotiate agreement with other surgical service providers to facilitate surgery during the remediation work, e.g. Royal Darwin Hospital used portable operating theatres installed on-site from the Defence Department.</li> <li>• Re-evaluate interchanging the IMRIS Operating Table after the operating theatre pendants have been replaced in all the other theatres.</li> </ul> | <b>Consequence Rating after Treatment</b><br>Moderate | <b>Likelihood Rating after Treatment</b><br>Unlikely | <b>Risk Level after Treatment</b><br>Medium |
|------------------------|--|--|------------------------------------|--------------------------------------|-----------------------------------|----------------------------------|--|---|--|---|

|                 |     |  |   |                           |                          |                           |                                  |  |   |  |                                   |
|-----------------|-----|--|---|---------------------------|--------------------------|---------------------------|----------------------------------|--|---|--|-----------------------------------|
| <b>Risk No.</b> | 11. | <b>Risk Description</b><br>What can happen and how   | <b>Current Controls</b><br>What do you already do to mitigate the risk? | <b>Consequence Rating</b> | <b>Likelihood Rating</b> | <b>Current Risk Level</b> | <b>Acceptability</b><br>Yes / No | <b>Risk Treatments</b>   | <b>Consequence Rating after Treatment</b> | <b>Likelihood Rating after Treatment</b> | <b>Risk Level after Treatment</b> |
|                 |     | <p><b>What:</b><br/>Degrading of the magnetic field for MRI and possible damage to staff and medical equipment from loose remnant small metal items or fragments</p> <p><b>Due to:</b></p> <ul style="list-style-type: none"> <li>Ferrous objects attracted to the magnet.</li> <li>Leaving small metal items or fragments after surgery in the MRI Neurosuite that will be attracted to the magnet when it starts to function, such as pins, screws, metal thread and fragments from implants.</li> <li>Likelihood of occurrence increase if this theatre is used for some other surgical procedures, e.g. implants, orthopaedic.</li> </ul> <p><b>Resulting in:</b></p> <ul style="list-style-type: none"> <li>Unclear images.</li> <li>Injury to staff</li> </ul> |   | Moderate                  | Possible                 | Medium                    |                                  | <ul style="list-style-type: none"> <li>Ensure all staff entering and using the MRI Neurosuite are trained and competent in using this theatre, including the cleaning, technical and clinical staff.</li> <li>Schedule appropriate surgical cases for this theatre, i.e. being particularly careful with surgical cases involving metal implants, metal components, screws, etc.</li> <li>Conduct a metal sweep with a magnetic roller at the end of each day for detecting and removing remnant small metal items or fragments of metal.</li> </ul> | Moderate                                  | Unlikely                                 | Medium                            |

**Baker, Jennie**

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**From:** Baker, Jennie  
**Sent:** Friday, 26 August 2011 11:18 AM  
**To:** Ringland, Alan; Cotterill, James  
**Subject:** FW: IMRIS Operating Theatre Table

FYI

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**From:** Van Lith, Martin  
**Sent:** Friday, 26 August 2011 10:20 AM  
**To:** Reid, Barbara; Scott, Adrian  
**Cc:** Baker, Jennie; Lang, Kellie  
**Subject:** FW: IMRIS Operating Theatre Table

Hello Adrian and Barbara

Response from [REDACTED] on designing a removable Operating Table and the other alternative for using interchangeable Table tops.

Looks as if there will be a removable Operating Table available in Australia from IMRIS suitable for the Neurosuite next year. Further details below.

He states that IMRIS are the only manufacturer of a magnetic resonance compatible Operating Table.

They do not have interchangeable Table tops but are working on a Table extension for lower spine surgery.

Kind regards

Martin Van Lith  
Business & Infrastructure Branch

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**From:** [REDACTED]  
**Sent:** Friday, 26 August 2011 6:54 AM  
**To:** Van Lith, Martin  
**Subject:** RE: IMRIS Operating Theatre Table

Dear Martin,

You're correct that over the past few years IMRIS has been working on a removable OR table. We're expecting to have a first generation version done at the end of this year. At that point we would then be able to file for Australian regulatory clearance. Assuming a 60 day approval process, we could install after that. However, it's important to please note that there would be some construction involved to replace the current table with the removable table. RF shield modifications would need to be done in addition to changes to the floor since the old table needs to be completely removed. We still don't have a price estimate yet but unfortunately it would likely be shockingly expensive.

Also, adding to the list of questions for the surgeons...do the surgeons want to use the iMRI for their spine cases or do they just want to use the room. The reason I ask is that IMRIS is the only manufacturer of a MR compatible OR table. No other table aside from the IMRIS table can be used intraoperatively with the magnet. Please note that we unfortunately don't have interchangeable table tops on our current table or really have plans to do so on future OR tables. For example, a position that can be achieved with a Jackson table could not be used intraoperatively with the magnet since it would not be able to fit the patient in the bore of the magnet for mid surgery imaging. We have however looked at a table extension to go lower down the spine but the position will always be horizontal flat (only



position that intraoperative imaging could be done). We currently don't have a table extension for lower spine but am working on it for future OR table versions.

Kindest Regards,  
[REDACTED]

IMRIS 

M. 204 291 6707 (Canada)  
M. 03 9005 6799 (Australia)  
M. 70 7847 7036 (South Korea)  
M. 852 8199 9245 (Hong Kong)  
E. [REDACTED]  
[www.imris.com](http://www.imris.com)

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**From:** Van Lith, Martin [mailto:Martin.VanLith@act.gov.au]  
**Sent:** August-24-11 5:29 PM  
**To:** [REDACTED]  
**Subject:** IMRIS Operating Theatre Table

[REDACTED]

I am following up on the telephone conversation a few days ago regarding the use of the IMRIS Operating Room Table other than for neurosurgery.

So far I have not been able to obtain the information you requested on specific details from the Operating Theatre staff on what other purpose they would like to use the Table, e.g. is it just for a longer table or a table that bends.

In the meantime I have read and sent on the literature that you sent to James Cotterill on 6 August 2011. Many thanks. I have passed on the literature to Barbara Reid, Executive Director, Division of Surgery and Oral Health.

I understand that IMRIS is designing a removable Operating Room Table, but that you expect it to be another year before it will be in production. The other alternative is for using interchangeable Table tops.

Your update on these issues would be appreciated.

Kind regards

**Martin Van Lith**



Coordinator, Accreditation and Risk Management, Systems & Reporting  
***Business and Infrastructure – committed to timely, responsive and client-focused services***

Ph: (02) 6205 0594 Email: <mailto:Martin.VanLith@act.gov.au>  
*Care Excellence Collaboration Integrity*

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This email, and any attachments, may be confidential and also privileged. If you are not the intended recipient, please notify the sender and delete all copies of this transmission along with any attachments

**Baker, Jennie**

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**From:** Staniforth, Robyn  
**Sent:** Friday, 2 September 2011 12:53 PM  
**To:** Baker, Jennie; Ringland, Alan; Scott, Adrian  
**Cc:** Geoghegan, Sean; Van Lith, Martin  
**Subject:** TRIM Correspondence : COR11/9072 : Minute from Barb Reid and Adrian Scott - Neurosuite IMRIS operating table at the Canberra Hospital  
**Attachments:** Minute from Barb Reid and Adrian Scott - Neurosuite IMRIS operating table at the Canberra Hospital.DOC

Hi Jennie and Alan

Please find attached the minute related to the Neurosuite IMRIS operating table at TCH.

Ag D-G has signed off but requested (in the future when known) "advice when an expected solution will be available".

Please keep me in the loop.

Thanks

R

-----< TRIM Record Information >-----

Record Number : COR11/9072  
Title : Minute from Barb Reid and Adrian Scott - Neurosuite IMRIS operating table at the Canberra Hospital

**SUBJECT: Neurosuite Operating Table at the Canberra Hospital**

To: Ian Thompson, Ag Director-General

Through: Lee Martin, Deputy Director-General TCH & Health Services  
Rosemary Kennedy, Ag Deputy Director-General Strategy & Corporate

From: Barbara Reid, Executive Director Surgery & Oral Health  
Adrian Scott, Ag Executive Director Business & Infrastructure

Date: 26 August 2011

**Purpose**

To advise you of the outcome of the Review of the IMRIS Operating Table at the Canberra Hospital; and  
To advise you of the risk management action taken.

**Background**

To make effective use of the operating theatres it is necessary to remove the operating table from the Neurosuite and replace it with a regular operating theatre table when neurosurgery is not scheduled.

Issues have arisen with the removal and re-installation (interchange) of the Intra-Operative Magnetic Resonance Imaging System (IMRIS) operating table since June 2011 when a trial to interchange the table was initiated.

The Operating Table is fixed to the theatre floor in order for the movable Magnetic Resonance Imaging (MRI) to safely and accurately image patients during surgery. The frequent inter-changing of the IMRIS operating table has raised staff concerns about the accuracy of the table's function and the possibility of injury to patients and staff.

A review of the Neurosuite IMRIS operating table was commissioned by Business & Infrastructure (B&I) to formally identify the risks associated with its interchange for use of the theatre for other surgical procedures.

**Issues**

The Review was completed on 22 August 2011 with findings identifying significant risks associated with the frequent interchange of the Neurosuite operating table. The risks identified are categorized mainly as extreme (3) and high (6) level and related to adversely affecting the accurate function of the table, abnormal wear and tear, re-installation error and the possibility of liability for patient and staff injury. Following the outcome of the Review the Executive Director Surgery & Oral Health requested removal of the operating table from the Neurosuite until the issue is permanently solved.

During the evening of Monday 22 August 2011 the IMRIS operating table was removed from the Neurosuite by Biomedical Engineering Services assisted by the IMRIS service technician.

IMRIS Inc has been requested to engineer a solution to enable the safe interchange of the operating table in the future.

### **Recommendation**

That you Note the information contained in this brief

*AGREED/NOT AGREED/NOTED/PLEASE DISCUSS*

Ian Thomson  
**Ag Director-General**  
**Health Directorate**

Adrian Scott  
Ag Executive Director  
Business & Infrastructure  
Strategy & Corporate

Barbara Reid  
Executive Director  
Surgery & Oral Health  
TCH & Health Services

August 2011

August 2011

Action Officer: **Martin Van Lith**  
Branch: Business & Infrastructure  
Extension: 5 0594

**Baker, Jennie**

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**From:** Cotterill, James  
**Sent:** Friday, 2 September 2011 2:01 PM  
**To:** Van Lith, Martin; Sommariva, Maurice; Geoghegan, Sean; Belle, Kyril; Williams, Horace; Ringland, Alan; Baker, Jennie  
**Subject:** FW: DIR 24353 - notification of investigation of device incident [SEC=UNCLASSIFIED]  
**Attachments:** DIR 24353 - notification of investigation of device incident.DOCX

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**From:** [Sandra.Byrne@tga.gov.au](mailto:Sandra.Byrne@tga.gov.au) [mailto:[Sandra.Byrne@tga.gov.au](mailto:Sandra.Byrne@tga.gov.au)]  
**Sent:** Friday, 2 September 2011 1:59 PM  
**To:** Cotterill, James  
**Subject:** DIR 24353 - notification of investigation of device incident [SEC=UNCLASSIFIED]

Please forward all responses to this email to [iris@tga.gov.au](mailto:iris@tga.gov.au). Please do not cc anyone else from the DVM/IRIS into the email.

Regards  
Sandra Byrne

Device Vigilance & Monitoring | Office of Product Review | Device Incident Report Investigation Scheme | Therapeutic Goods Administration  
Phone: (02) 6232 8695 | Fax: (02) 6203 1713 | E-mail: [sandra.byrne@tga.gov.au](mailto:sandra.byrne@tga.gov.au)  
Postal address: PO Box 100 Woden ACT 2609 | Courier address: 136 Narrabundah Lane Symonston ACT 2606

\*\*\*\*\*

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**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**Australian Medical Device**  
**Incident Report Investigation Scheme**

James Cotterill  
Canberra Hospital  
Canberra ACT

Dear James Cotterill

**DEVICE INCIDENT REPORT DIR 24353 - MRI system, full-body, superconducting magnet/Imris Inc**

We thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Therapeutic Device Incident Reporting Database, where it will be evaluated against any previous incidents with the same or similar devices. We have also contacted the product sponsor requesting details of any similar reports.

This process may take some time, but be assured we will advise you of the final outcome of our investigations. However, should you have any queries in the meantime, please do not hesitate to contact me on (02) 6232 8695.

Thank you for your participation in the Medical Device Incident Report Investigation Scheme. Additional forms are enclosed.

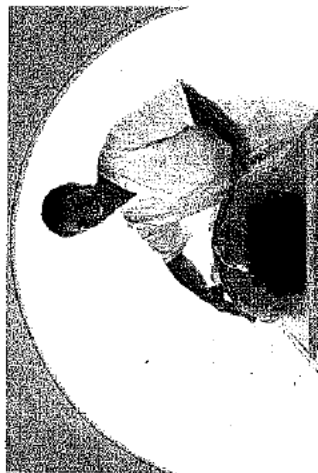
Yours sincerely

Sandra Byrne

Incident Report and Investigation Scheme  
Market Vigilance and Monitoring Section  
Therapeutic Goods Administration

02/09/2011





# MAGNETOM Family Creating the future of MRI

Hospital The Camberra Hospital  
 Address Yamba Drive  
Carran ACT 2606

System Espre  
 Gradient configuration \_\_\_\_\_  
 System No. \_\_\_\_\_  
 Serial No. 30998  
 Connected cameras PACS  
 Service hotline 1800 227 557 (Siemens)

Important telephone numbers  
IMRIS Customer Service 1866 475 0525

Siemens Service  
 \_\_\_\_\_

MAGNETOM VERIA  
Creating the Future of MRI

| No | Date     | Patient Name | Fibre scan | Diagnosis | Billing Code | Program                             | Coil | QE | Store | Operator |              |
|----|----------|--------------|------------|-----------|--------------|-------------------------------------|------|----|-------|----------|--------------|
| 1  | 6/9/10   | [REDACTED]   |            |           |              | Tumor resection                     |      |    |       |          | Dr. Fuller   |
| 2  | 7/9/10   | [REDACTED]   |            |           |              | Tumor resection                     |      |    |       |          | Dr. Chandran |
| 3  | 8/9/10   | [REDACTED]   |            |           |              | Tumor resection                     |      |    |       |          | Dr. Halston  |
| 4  | 12/9/10  | [REDACTED]   |            |           |              | Tumor resection                     |      |    |       |          | Dr. McDowell |
| 5  | 1/11/10  | [REDACTED]   |            |           |              | Tumor resection                     |      |    |       |          | Dr. McDowell |
| 6  | 13/12/10 | [REDACTED]   |            |           |              | Biopsy of tumor                     |      |    |       |          | Dr. McDowell |
| 7  | 24/2/11  | [REDACTED]   |            |           |              | Tumor resection<br>Trans-sphenoidal |      |    |       |          | Dr. McDowell |

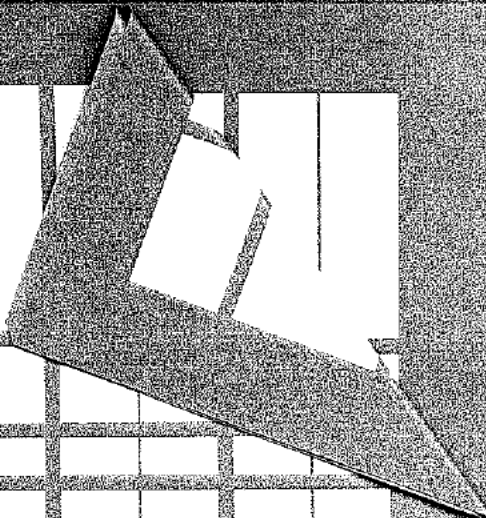
MAGNETOM Family  
 Creating the future of MRI

| No. | Date    | Given Name, Date of Birth | Diagnosis | Referring Code                       | Program | Coll. | Q. Score | Comment      |
|-----|---------|---------------------------|-----------|--------------------------------------|---------|-------|----------|--------------|
| 8   | 10.3.11 | [Redacted]                | iMRI      | Tumour Resection                     |         |       | ✓ P      | Dr. McDowell |
| 9   | 22.3.11 | [Redacted]                | iMRI      | Tumour Resection<br>trans-sphenoidal |         |       | ✓ P      | Dr. Fuller   |
| 10  | 18.4.11 | [Redacted]                | iMRI      | Trans sphenoidal<br>tumour resection |         |       | ✓ P      | Dr. McDowell |
| 11  | 25/5/11 | [Redacted]                | iMRI      | Trans sphenoidal<br>tumour resection |         |       | ✓ P      | Dr. McDowell |
| 12  | 25/7/11 | [Redacted]                | iMRI      | Tumour Resection                     |         |       | P        | Dr. McDowell |
| 13  | 10/8/11 | [Redacted]                | iMRI      | Tumour Resection                     |         |       | P        | Dr. McDowell |
| 14  | 1.6/11  | [Redacted]                | C spine   | C4 quadriparesis                     |         |       | P        |              |



MAGNETOM Family  
Creating the future of MRI

| No. | Date    | Patient Name | Diagnosis | Study Code                            | Program | Four | Store | Operator    |
|-----|---------|--------------|-----------|---------------------------------------|---------|------|-------|-------------|
| 15  | 16/8/11 | [REDACTED]   | iMRI      | Transphenoidal<br>tumor resection     |         |      | ✓     | Dr Fuller   |
| 16  | 5/3/12  | [REDACTED]   | iMRI      | Tumor resection                       |         |      |       | Dr McDowell |
| 17  | 7/3/12  | [REDACTED]   | iMRI      | Transphenoidal<br>pituitary resection |         |      | ✓     | Dr McDowell |
| 18  |         | [REDACTED]   |           |                                       |         |      |       |             |
| 19  |         | [REDACTED]   |           |                                       |         |      |       |             |
| 20  |         | [REDACTED]   |           |                                       |         |      |       |             |
| 21  |         | [REDACTED]   |           |                                       |         |      |       |             |



**Kirchner, Horst**

**From:** Kirchner, Horst  
**Sent:** Monday, 12 September 2011 3:24 PM  
**To:** JasonSmith, Rhona; Silec, Mario (Supply); Lang, Kellie  
**Subject:** RE: Theatres Lights & pendants Program of Works  
**Attachments:** Photo0154.jpg; Photo0155.jpg; Photo0143.jpg

Rhona,  
I'm still waiting for lqon, to come back to me.

I had a think about the Imris table issue, where there is a concern about the Hydraulic pipes in the floor being bent over, which in time will cause the stainless steel to weaken, If we raise the bump on the stainless steel floor cover, so that the pipes aren't bent, we overcome that issue.  
The pictures attached show the Jackson table in place and the cover.

cheers

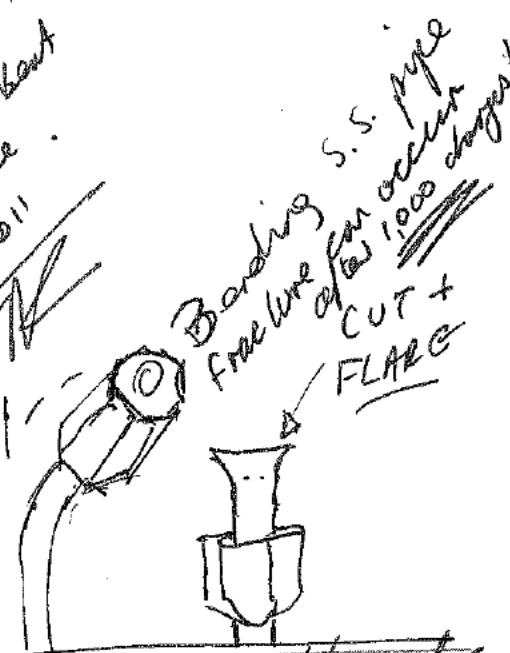
**Horst Kirchner**  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363  
mob [REDACTED]

**Out of office Fridays**

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Care Excellence Collaboration Integrity



Note  
HK also suggested that the floor pipes be cut below the elbow and new fittings made so that pipes are not bent when IMRIS is not in use.  
December 2011



FLOOR

the need of a safety valve in ??? very low pressure  
The actual length of air can be checked on the reservoir

**From:** JasonSmith, Rhona  
**Sent:** Friday, 9 September 2011 12:49 PM  
**To:** Kirchner, Horst  
**Subject:** FW: Theatres Lights & pendants Program of Works  
**Importance:** High

Hi Horst

Did the meeting happen? Any idea what the plan is?

Cheers  
Rhona

Rhona JasonSmith  
Assistant Director of Nursing Perioperative Services  
The Canberra Hospital  
ph (02) 62443051  
fx (020) 6244 3348

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**From:** Kirchner, Horst  
**Sent:** Monday, 29 August 2011 8:01 AM  
**To:** JasonSmith, Rhona

**Cc:** Lang, Kellie; Silec, Mario (Supply); Bonato, Mark  
**Subject:** RE: Theatres

Rhona, I had a meeting with Iqon on Thursday, they will be presenting a comprehensive plan for the next install session, hope fully this week.

regards

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363

mob. [REDACTED]

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*Care Excellence Collaboration Integrity*



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**From:** JasonSmith, Rhona  
**Sent:** Friday, 26 August 2011 11:02 AM  
**To:** Kirchner, Horst  
**Cc:** Lang, Kellie  
**Subject:** RE: Theatres

Hi Horst

I am wondering if I could please have a more comprehensive update on the replacement of the lights and pendants. I see you have mentioned January 2012. Are we still looking at 4 weeks for each theatre? And can only do 2 max at a time? If this is the case then we would only get two theatres completed? Just wondering what the plan is.

I can make a theatre available routinely from now, starting with OR7. Can we please consider a rolling program of works?

Thanks  
Rhona

Rhona JasonSmith  
Assistant Director of Nursing Perioperative Services  
The Canberra Hospital  
ph (02) 62443051  
fx (020) 6244 3348

Care Excellence Collaboration Integrity

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**From:** Kirchner, Horst  
**Sent:** Tuesday, 16 August 2011 9:19 AM  
**To:** Luke Edwards; JOMAA Anas  
**Cc:** JasonSmith, Rhona; Simon, Helmut; Lamech, James; Grovenor, Priya; Clark, David; Swain, Rob  
**Subject:** Theatres

Luke, as discussed earlier,

IT Cabinet,

We need to check to power supply, and when we can access the store area to install the Data Cabinet for IT, if we need to isolate the power to bring the cabinet on line, we will need to agree a best time scenario from Rhona.

Theatre Pendants & Lights,

Please investigate the availability of contractors to roll with the install program for January 2012, please review the costs and materials to complete as many units as possible, as once again our access window is limited.

With any new works we will have to ensure that Work Place Safety, are comfortable with our process, so allow reasonable time for us to get the sign off.

regards

*Horst Kirchner*  
Business & Infrastructure  
Strategic Support  
Bldg. 6, L3, TCH  
62050363

mob. [REDACTED]

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# IMRIS

September 9, 2011

Ms Kate Jackson  
Executive Director, Division of Critical Care and Imaging  
Canberra Hospital  
Canberra, Australia

## URGENT Recall for Product Correction

**IMRIS Operating Room Table ORT100**

**(ARTG Number: 136622)**

Dear Ms Jackson,

It has recently come to our attention that the rotary locking mechanism for the ORT100 table may come loose over time and through multiple uses resulting in some side to side wiggle of the table. For this reason, it is recommended that the lock be tested prior to each use of the table, and should any movement be detected, IMRIS be called immediately to make adjustments.

As a precautionary measure, IMRIS Inc has redesigned the rotary lock mechanism to eliminate this problem, and will shortly be replacing the lock mechanism on your OR table with the new version.

We expect to have the parts available to perform this update by September 16<sup>th</sup> at which time we will be contacting you to schedule the update. The replacement of the locking mechanism will be completed on site in your operating theatre, and is expected to take no longer than 1 full day to complete.

Please note that there is no action required by you or Canberra Hospital at this time as the OR table in question has been removed from the OR by your staff in order to enable use of the OR for alternate procedures. The table will be updated prior to the reinstallation in the suite.

The Therapeutic Goods Administration has been advised of this action.

If you have any questions regarding this update you may contact [redacted] the IMRIS 24 hour call line at 1- 866-475-0525 or by email at [redacted]. Alternatively you may contact [redacted].

IMRIS Inc apologizes for any inconvenience this may cause.

Sincerely,

[redacted signature block]

cc. Kellie Lang, Anna Thornton, Cameron Robertson, Rhona Jason Smith

[redacted distribution list]



**Baker, Jennie**

---

**From:** Lang, Kellie  
**Sent:** Monday, 12 September 2011 10:13 PM  
**To:** Silec, Mario (Supply); Baker, Jennie  
**Subject:** FW: Imris Table rotary Lock Recall.  
**Attachments:** IMRIS Recall Letter with TGA.pdf

**Importance:** High

FYI

---

**From:** [REDACTED]  
**Sent:** Monday, 12 September 2011 12:45  
**To:** Jackson, Kate  
**Cc:** Lang, Kellie; [REDACTED] Cotterill, James; JasonSmith, Rhona  
**Subject:** Imris Table rotary Lock Recall.  
**Importance:** High

Hi Kate


As discussed over the phone please find attached the Recall letter for the IMRIS table which is currently not in use. I have copied in James Cotterill and contact him to arrange access for the replacement components to be installed in the next few days.

If you have any question please do not hesitate to contact me.

PH [REDACTED]

Regards

[REDACTED]  
**IMRIS**   
[www.imris.com](http://www.imris.com)

 Please consider the environment before printing this e-mail.

This email has been scanned by the IMRIS Email Security System

# IMRIS

September 9, 2011

Ms Kate Jackson  
Executive Director, Division of Critical Care and Imaging  
Canberra Hospital  
Canberra, Australia

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[REDACTED] the IMRIS 24 hour call line at 1- 866-475-0525 or by email at  
[REDACTED] Alternatively you may contact [REDACTED]

IMRIS Inc apologizes for any inconvenience this may cause.

Sincerely,

[REDACTED]

cc. Kellie Lang, Anna Thornton, Cameron Robertson, Rhona Jason Smith

[REDACTED]

