

Acknowledgement and Receipt Form: Response is required

Please complete this form and e-mail a copy to service@research-instruments.com

Name of Your Company : LabIVF Asia Pte Ltd

Address of Your Company : Accounts Department 1 Bukit Batok Crescent #03-13/14
WCEGA Plaza 658064 SINGAPORE

Contact Name/Title : Chua Chiew Ling

Phone Number : [65] 6 8967098

E-mail Address : chuac@labivf.com

Affected Product Information: Include information that is applicable for affected product.

Part Number	Product Description	Serial Number
6-54-110	INTEGRA 3 micromanipulation System with Thermosafe	78
6-54-110	INTEGRA 3 Micromanipulation System	
6-54-150	Upgrade of any Manipulation System to INTEGRA 3, with Thermosafe	
6-54-160	Upgrade of any Manipulation System to INTEGRA 3 (without Thermosafe) T	

Please inform us of any anomalies in this list i.e. serial numbers not accounted for, etc.

I have read and understand the recall instructions provided in the 7th March 2016 letter.

Please tick **Yes** X **No**

If you have any questions or concerns please contact Research Instruments Customer Service on +44 (0) 1326 372 753 or contact us via e-mail at service@research-instruments.com.

Signed:

Date: 12 April 2016

Print Name: Chua Chiew Ling

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07 March 2016

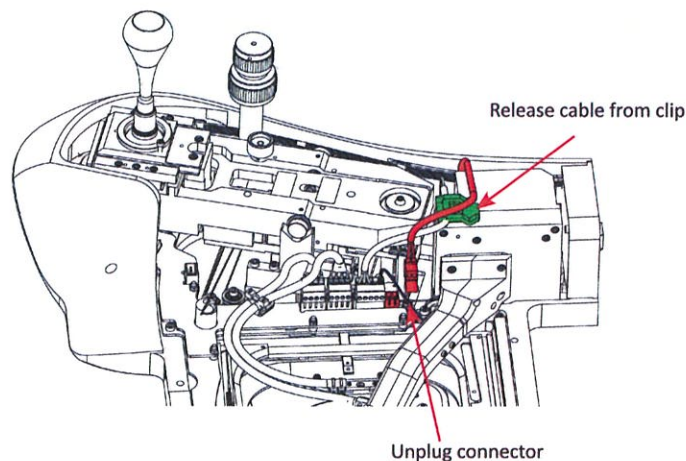
URGENT: MEDICAL DEVICE RECALL

Dear Valued Research Instruments' Customer

Research Instruments is voluntarily recalling the power supply cable for the Integra 3™ micromanipulator. Research Instruments internal testing has discovered a minor materials fault with the power supply cable (2-54-031). Our records show the affected products were shipped to your facility.

The Integra 3 micromanipulator has been designed to precisely position microtools under a microscope whilst maintaining specimen temperature during Assisted Reproduction Techniques (ART) such as Intracytoplasmic Sperm Injection (ICSI) and Intracytoplasmic Morphologically-selected Sperm Injection (IMSI).

In rare instances, the power supply cable may cause the loss of power to the heating control of the Integra 3 and the temperature function to be disabled. In order to mitigate any chance of down time for your customers' Integra 3 micromanipulator, we recommend this power supply cable is replaced by one of your trained technical engineers. We anticipate this correction will take approximately 10 minutes depending on accessibility.



To initiate the replacement of the power cable, please follow the steps below:

1. Acknowledge receipt of this letter by completing the attached **Acknowledgement and Receipt Form**
2. Review your sales and traceability records to identify users of the Integra 3 model. Please note, you are contractually obligated to maintain traceability records for the sale of all RI products and this information should be easily available.
3. Promptly contact all Integra 3 users and inform them of this Correction Notification
4. Promptly arrange the replacement of the cable on each Integra 3 by one of your trained technical engineers within 3 months of the date of this letter.
5. Record each replacement on the Product Correction Completion Form (PCCF) enclosed. The serial number of each Integra 3 can be found on the back panel.



6. Send a copy of the completed PCCF to Research Instruments within 3 months of the date of this letter.

Instructions (2-54-031-IM) are enclosed with the replacement cables. These instructions and a film showing the replacement process can also be downloaded from the Research Instruments Distributor Website (<http://distributor.research-instruments.com>) and the film can be also viewed at <https://youtu.be/5kclgyMh4Vg>.

If you require more cables, or any advice or assistance in order to complete any aspect of this correction, then please contact service@research-instruments.com.

If you have any questions or concerns please contact Research Instruments Customer Service on +44 (0) 1326 372 753 (Monday through Friday 8.00 – 16.30 GMT) or contact us via e-mail at service@research-instruments.com.

Thank you for your cooperation

John Mitchell
Quality and H&S Manager



Integra 3 Internal Power Cable Replacement

This document provides instructions to replace the internal power cable in an Integra 3. It is usually possible to perform this procedure without removing the Integra 3 from the microscope. However, if it is necessary to gain better access the Integra 3 can be removed from the microscope. The procedure for doing this is described in the Integra 3 Installation and Service Manual (6-54-701IM).

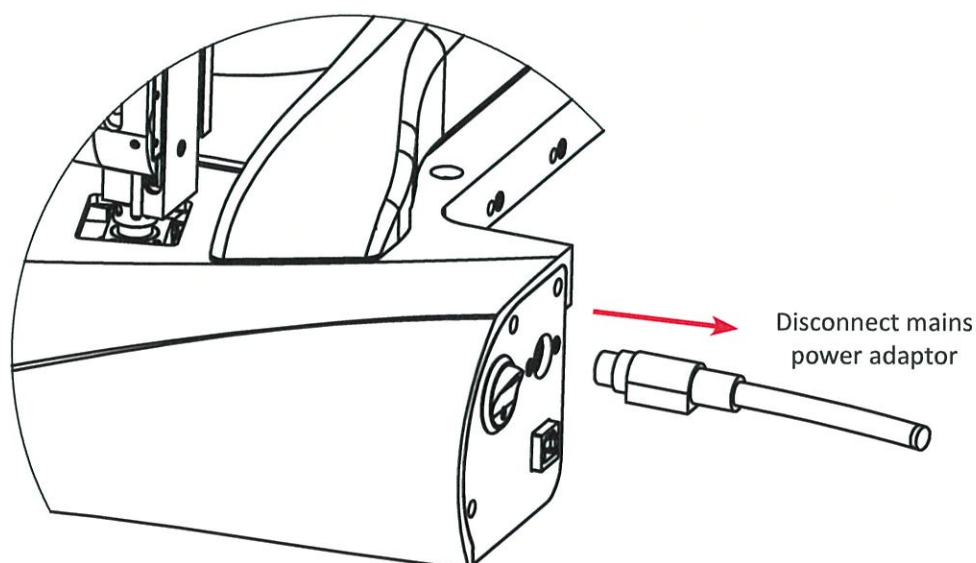
Applicable Part Numbers

Part Number	Description
6-54-110	Integra 3 with Heated Metal Insert
6-54-100	Integra 3 with Heated Metal Insert and Thermosafe™
6-54-150	Integra 3 Upgrade with Thermosafe
6-54-160	Integra 3 Upgrade without Thermosafe
2-54-031	Power Cable Assembly

Before carrying out this procedure ensure that all sharp or dangerous objects are removed from the work area, and that there is sufficient access to the underneath and back right hand side of the Integra 3. It may improve access if the microscope/Integra 3 is rotated on the bench.

Replacement Procedure

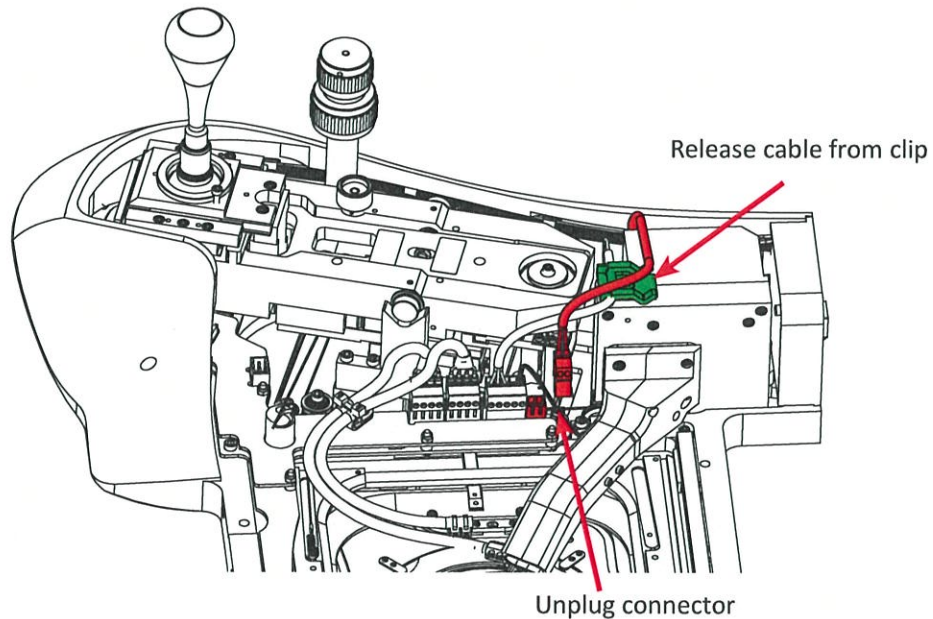
1. Switch off the Integra 3 power adapter at the mains then disconnect the mains power adapter from the Integra 3 rear panel.



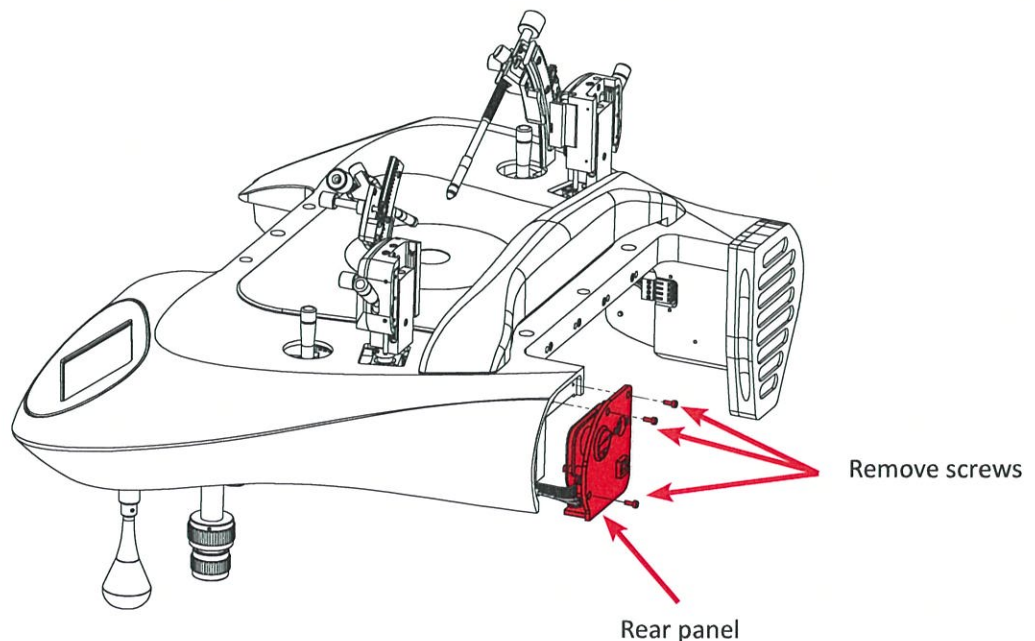
2. The power cable is located underneath towards the rear of the Integra 3 (the cable, connector and socket are shown in red below).

Look underneath the Integra 3 for the row of orange connectors/sockets shown below. Unplug the 2-way connector nearest the back which contains only a red and black wire. There are no clips to release. Ensure that the correct connector is unplugged.

Release the power cable from underneath the white clip located on the surface of the Thermosafe Heater Module, (the cable clip is shown in green below), and from any other clips that retain the cable.

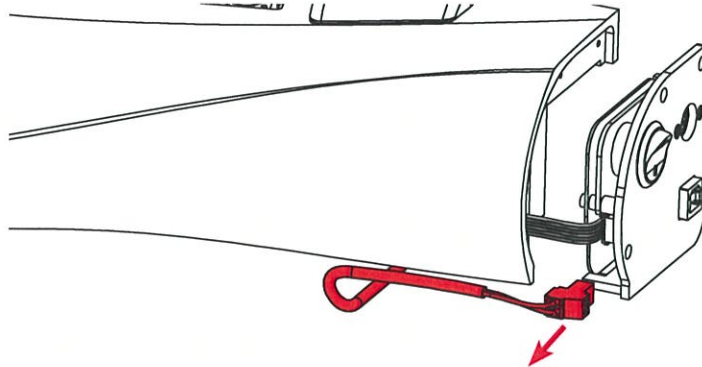


3. Remove the three M2.5 screws that hold the rear panel to the Integra 3. Keep these as they will be needed later). Gently move the rear panel backwards, tilting downwards slightly in order to gain access to the connectors. Do not pull too hard as this may damage the cables.



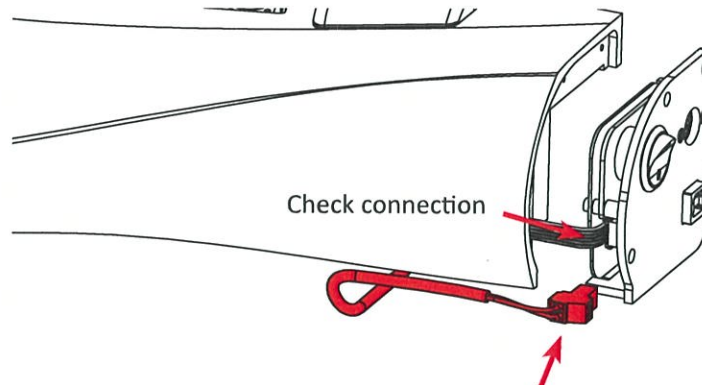
4. Unplug the 2-way orange power cable connector, the lower of the two cables, by pulling on the connector. There are no clips to release. If you find it difficult to get hold of the connector it may be necessary to pull on the cable.

Take care not to damage or pull on the other cable attached to the rear panel assembly.

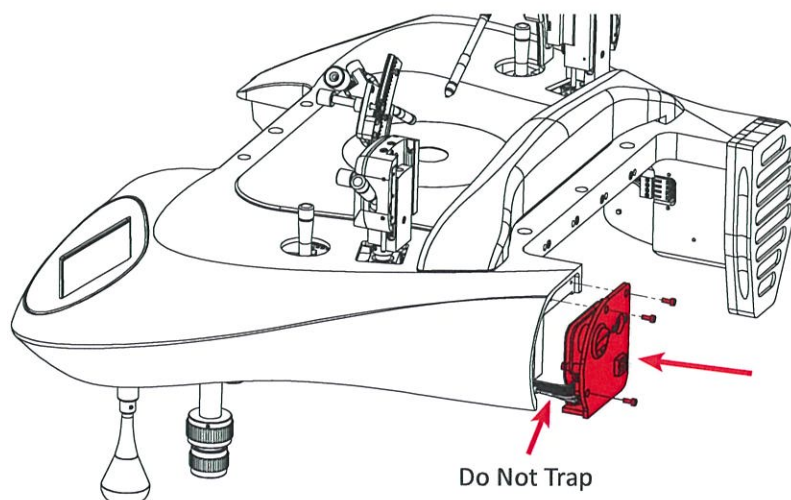


5. Once the cable is removed, plug a new power cable (Part No. 2-54-031) into the rear panel assembly. Both ends of the cable are identical so either end can be used. Note that the connector can only be plugged in one way round: the screw terminals in the connector should face towards the rear panel. When inserting the connector, a positive click should be heard as the connector clips into position. It is important that the connector is fully inserted.

Take care not to damage or pull on the other cable attached to the rear panel assembly. Check that the red connector is still clipped firmly into its socket.



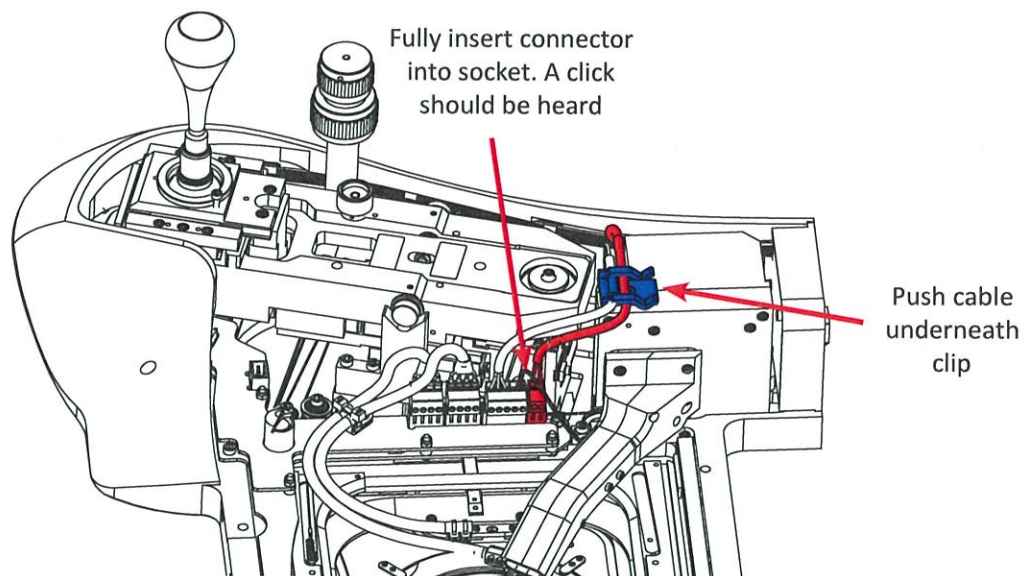
6. Route the cable behind the Thermosafe Heater Module, then refit the rear panel using the three M2.5 screws. Take care not to trap the cables.



7. Working beneath the Integra 3, plug the 2-way orange connector on the new power cable into the 2-way socket nearest the back of the Integra 3. Note that the connector can only be plugged in one way round: the screw terminals in the connector should face towards the centre of the Integra 3. When inserting the connector a positive click should be heard as the connector clips into position. It is important that the connector is fully inserted.

Route the cable underneath the cable clip on the surface of the Thermosafe Heater Module.

8. Check that all the connectors are correctly fitted then re-connect the power adapter to the Integra 3 and mains supply before switching on the Integra 3.
9. Verify that all heating systems attain the set-point temperature. It is not possible to affect the calibration by changing the power cable. However, it is recommended that calibration is checked after performing any service activity on the Integra 3. Follow the procedure in the Integra 3 User Manual 6-54-701UM to do this.



10. If a PC is connected, verify that the communications with the Integra 3 function correctly. To do this, open the RI Viewer™ software and verify that the Start/Stop Video Recording Buttons and Capture Still Image Buttons function correctly.