RI Integra 3™

User Manual

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CE 2797 Rx Only

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CooperSurgical®

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SECTION 1 - PREFACE

Thank you for choosing the Integra 3.

This manual provides all necessary information to use the Research Instruments Integra 3 micromanipulation system. The system should be operated by trained personnel only. All sections of this manual should be read and understood fully before any operation of the system. Please see the Intended Use for more information.

If the operator is unsure of any of the information contained in this manual, they should contact Research Instruments or an appointed representative before attempting to use this equipment.

In no event does Research Instruments Ltd (RI) assume the liability for any technical or editorial errors of commission, or omission; nor is Research Instruments liable for direct, indirect, incidental, or consequential damages arising out of the use or inability to use this manual.

RI is constantly updating its products, and therefore reserves the right to introduce changes in design, equipment and technical features at any time.

The Integra 3 manual belongs with the micromanipulation system and should be passed on with the Integra 3 micromanipulation system if relocated to another clinic.

The use of ™ in this manual indicates a trademark of Research Instruments Ltd. Any other brand names, referred to in this manual, are trademarks of their respective owners.

A hard copy of this user manual is available on request.

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SECTION 2 - INTRODUCTION

Intended Use

To precisely position microtools under a microscope whilst maintaining sample temperature during Assisted Reproductive Technology (ART) procedures such as Intracytoplasmic Sperm Injection (ICSI).

Intended Patient Population

For those who require assisted reproductive treatments to improve their chances of a healthy pregnancy and outcome.

Medical Condition

The medical condition is infertility and genetic disease.

Clinical Benefit

The clinical benefit of using this medical device during ART procedures is to improve the patient's chances of a viable pregnancy and long-term health of the offspring.

Intended Environment of Use

For use in a controlled clinical environment where Assisted Reproductive Techniques (ART) are used.

Intended User

Trained clinical professional working in Assisted Reproductive Techniques (ART) with locally relevant qualifications.

Obligation to Inform

Any serious incident that has occurred in relating to this device should be reported to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

USA ONLY Ref: FDA 510(k) K003142

The RI TDU500* Micromanipulator for Assisted Reproduction is used to accurately position microtools under a microscope for the techniques of Assisted Reproduction.

The RI Integra is a configuration comprising two TDU500* micromanipulators, two air syringes and temperature control system within a single housing.

Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained and certified in its use.

* TDU500 has now been replaced by current model TDU3.

Applicable indications for use are subject to the regulations of the country into which the device is sold. Availability of an Integra 3 Micromanipulator for clinical use is dependent on the regulatory approval status of the Integra 3 Micromanipulator in the country the device is intended to be sold into.

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

Microscope Compatibility

Zeiss Axiovert 40/100/200, Axio Observer, Axio Vert.A1

Nikon TMD, Diaphot 200/300, TE200/300, TE2000, Ti

Leica DMIRB, DMI3000B/4000B/6000B, DMIL, DMi8

Olympus IMT2, IX50/70, IX51/71/81, IX53/73/83

Installation

Installation of the Integra 3 system should be carried out by a CooperSurgical technician or other CooperSurgical authorised personnel. Incorrect installation could result in poor pipette set-up and an overall poor performance.

Relocation of this system should be treated as a re-installation and should, therefore, be carried out by authorised personnel.

Please note that installation and servicing is covered separately in the Integra 3 Installation and Service Manual (6-54-701IM). Users within the USA will not be provided with Integra 3 Installation and Service Manual.

The only user-serviceable parts are those detailed in the Troubleshooting and Care and Maintenance Sections.

Packaging and Handling Requirements

To prevent transit damage to the equipment, the toolholders and, where applicable, syringes are packed separately and must be fitted before operating the instrument.

SECTION 3 - SAFETY WARNINGS

Warnings

WARNING To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

WARNING Not to be used in a patient environment.

WARNING Do not modify this equipment without authorisation of the manufacturer.

Cautions

Ensure that the mains power supply adaptor is prevented from falling off the bench as this is likely to cause damage to equipment.

This indicates cautionary text which should be followed to avoid injury to users or damage to samples.

The system should be operated by qualified and trained personnel only.

DO NOT disassemble or modify any part of the Integra 3, or substitute any component for any other. Doing so may result in damage to specimens, and this voids the warranty and/or service contract.

DO NOT operate unless properly mounted to a microscope.

The microscope itself must be maintained to a high standard. Problems such as worn focus mechanisms or an insecure video camera may lead to unreliable focus and image stability, and could lead to embryo damage.

ONLY use the power cable and power supply adaptor supplied with the system.

The cable to the power supply is the Disconnect Device for this equipment. To remove all electrical power from this product, disconnect the power cable from the electrical outlet. Equipment should be positioned so as to allow easy access to the power cable. The appliance coupler or mains plug is used as the disconnect and must remain readily operable.

Guidance & Manufacturer's Declaration - Electromagnetic Emissions (IEC 60601-1-2)

The Integra 3 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Integra 3 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The Integra 3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Integra 3 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. **Warning:** This equipment/ system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Integra 3 Or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This equipment is deigned to be used by professionals in a laboratory environment and conforms to IEC 60601-1-2 electromagnetic compatibility for professional use, however it is recommended that Portable RF communications equipment (such as mobile phones, hand held mobile radios etc) should not be used within 30cm of this device as it could interfere with the performance of the Integra 3.

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Integra 3 requires continued operation during mains power interruptions, it is recommended that the Integra 3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3.0 A/m 50/60Hz	3.0 A/m 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: *UT* is the a.c. mains voltage prior to application of the test level.

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electro magnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Integra 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5/V_1] \sqrt{p}$ $d = [3.5/V_1] \sqrt{p}$ 80MHz to 800MHz $d = [3.5/V_1] \sqrt{p}$ 800MHz to 2.5GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Integra 3 is used exceeds the applicable RF compliance level above, the Integra 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Integra 3.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

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Glossary of Safety/Information Symbols

Source: ISO 15223-1, BS EN 60601-1

Symbol	Meaning
CE 2797	In accordance with Annex II of the European Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC
Rx Only	Caution: US Federal law restricts this device for sale to or on the order of a licensed healthcare practitioner
EC REP	Authorized representative in the European Community
	Consult instructions for use
	Consult instructions for use
	WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.
	CAUTION: Indicates a potentially hazardous situation which, if not avoided, could result in a minor or moderate injury.
	Manufacturer
	Date of manufacture
MD	Medical device
REF	Catalogue or Part number

SN	Serial number
LOT	Batch code
UDI	Unique Device Identifier
	Do not dispose of product with normal waste. Disposal of according to EU WEEE Directive
	Direct current (DC)
	This way up
	Fragile, handle with care
	Stacking limited to 3 units
	Keep dry

SECTION 4 - PRODUCT OVERVIEW

Welcome to the user manual for the Research Instruments Integra 3 micromanipulation workstation. This manual covers set-up, operation and maintenance of the workstation. Please note that installation and servicing is covered separately in the Integra 3 Installation and Service Manual (6-54-701IM). Users within the USA will not be provided with Integra 3 Installation and Service Manual.

The Integra 3 provides a means of micromanipulating samples placed under a microscope whilst maintaining sample temperature when performing assisted reproduction techniques (ART).

An Integra 3 system consists of a baseplate which fits to a microscope, a heated stage, two mechanical micromanipulators and two micropipette holders. The system also includes syringes to apply suction and pressure. SAS air syringes are supplied as standard, but the SOS oil syringe or SAS-SE fine control air syringe are available on request. Optional components include a double toolholder, an ITO heated glass insert and an air heating system which is configured according to the customer's microscope. All heating systems are electrically powered.

Movement (micromanipulation) is controlled by mechanical means only with levers which provide both coarse (XY) and fine (XYZ) control. Both temperature and movement are controlled manually by the user.

Cautions

> **ONLY** use the power cable and power supply adaptor supplied with the system.

System Components

* Subject to order configuration

Figure 4-1

The following tables give part numbers of system components and microscope adaptors. All parts are supplied or manufactured by Research Instruments Ltd.

Integra 3 System Component Part Numbers

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Part Number	Description
5-54-300	PL3, Left Hand
5-54-320	PL3, Right Hand
5-54-100	Baseplate Assembly
6-54-400	TDU3 (x2)
6-27-562	MPH (x2)
5-54-290	Heated Stage Insert (Heated Metal Insert, 25mm Diameter)*
5-54-282	Heated Stage Insert (ITO Heated Glass Insert)*
2-00-893	12V 11A Medical Power Supply Adaptor
5-50-170	Handrest (x2)
6-34-520	SAS Air Syringe*
6-34-530	SAS-SE Air Syringe*
6-34-700	SOS Oil Syringe*

13.

*Subject to order configuration

Integra 3 System Microscope Adaptor Part Numbers

Note: The front and rear adaptors are specified according to microscope. Part numbers given below include the front adaptor, rear adaptor and fixing screws as required.

Part Number	Description
5-54-120	Olympus IX51/71, IX53/73/83
5-54-140	Olympus IX50/70
5-54-134	Olympus IMT2
5-54-122	Nikon TE200/300, TE2000, Ti, Diaphot 200/300
5-54-136	Nikon TMD
5-54-142	Leica DMIL
5-54-124	Leica DMIRB/DMI3000B/4000B/6000B/DMi8
5-54-128	Zeiss Axiovert 100/200, Axio Observer, Axio Vert.A1
5-54-144	Zeiss Axiovert 40

Please consult RI for fitments to microscopes not listed above.

Hardware Overview

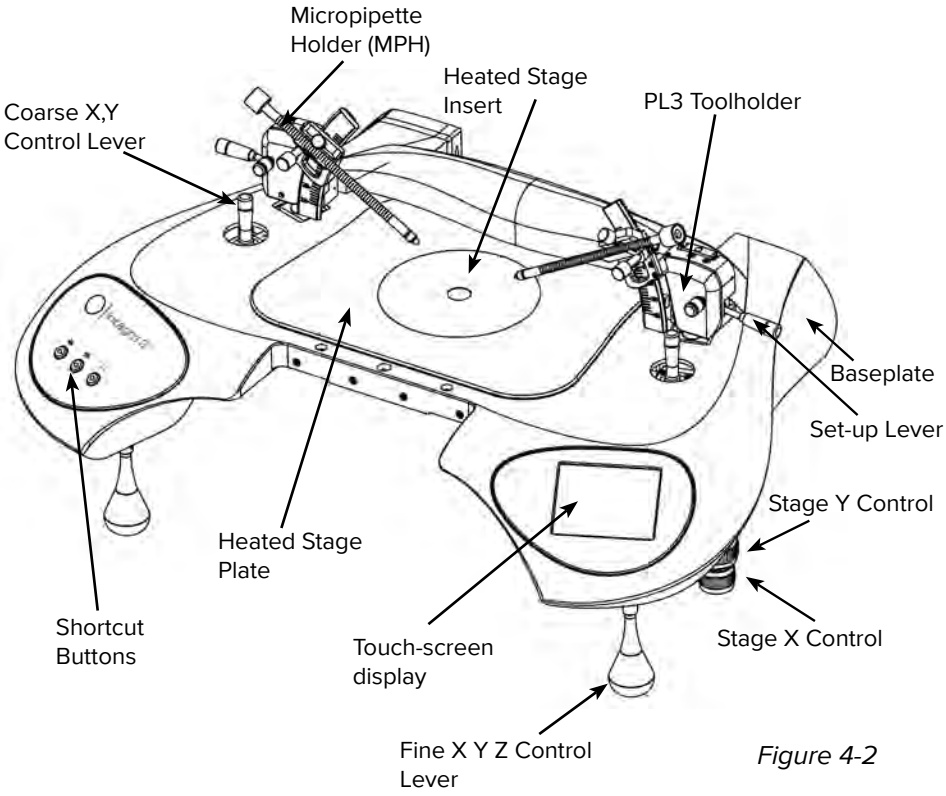


Figure 4-2

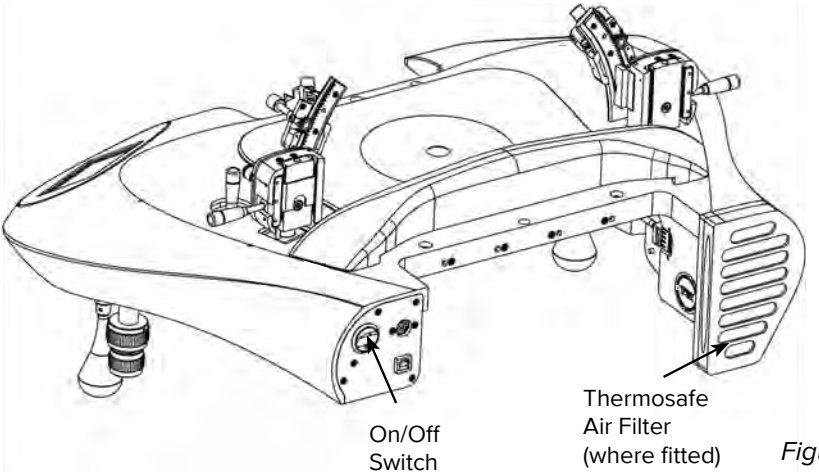


Figure 4-3

Integra 3 Specification Table

Part	Description
Manipulator Fine Control	X, Y and Z movement from one lever (X = side to side, Y = front to back, Z = up and down) ≤ 1µm resolution in X and Y 0.75mm X and Y travel, 5mm Z travel
Manipulator Coarse Control	X and Y movement 10 micron resolution 4mm X and Y travel
PL3 Toolholders	Pipette location Pipette angle adjustment 16 to 43 degrees
Heating Systems (configuration dependent)	Heated Metal Insert: 25mm ITO Heated Glass Insert Thermosafe Air Heating System
Temperature Controller	Accuracy: better than ±0.1°C when calibrated against known reference. 4. Displayed resolution: 0.1°C 5. Setpoint Temperature Range: 30-45°C 6.
Displays	3.5” LCD touch screen display for temperature control 7.
Connectivity	USB Type B socket for connection to PC running RI Viewer or RI Witness software (where used). Refer to software manual for further information. 8. 9. Connected PC to be compliant with IEC 60950-1
XY Stage	Aluminium Heated Stage Plate 40mm travel in X and Y
Syringes	Choice of SAS (air), SAS-SE (air) and SOS (oil)
Dimensions	Footprint (not including microscope) 11. Width 56cm, depth 38cm
Weight	Maximum weight of microscope mounted components (excluding front and rear adaptors): 10.4kg Actual weight is configuration dependent
Mains Power Adaptor	Input: 100-240VAC, 50-60Hz, Max. 1.8A, Class I Output: 12VDC, Min. 11A (132W)
Operating Conditions	Temperature: 15°C (59°F) to 40°C (104°F) 14. Humidity: 15% to 85% RH (non condensing) Pressure Range: 70kPa to 108kPa
Micropipette Compatibility	Compatible with Research Instruments micropipettes (or other industry standard 1mm OD micropipettes of equivalent specification).
Storage/Transport Conditions	Temperature: -40°C (-40°F) to 60°C (140°F) Humidity: 15% to 85% RH (non condensing) Pressure Range: 70kPa to 108kPa

SECTION 5 - BASIC OPERATION

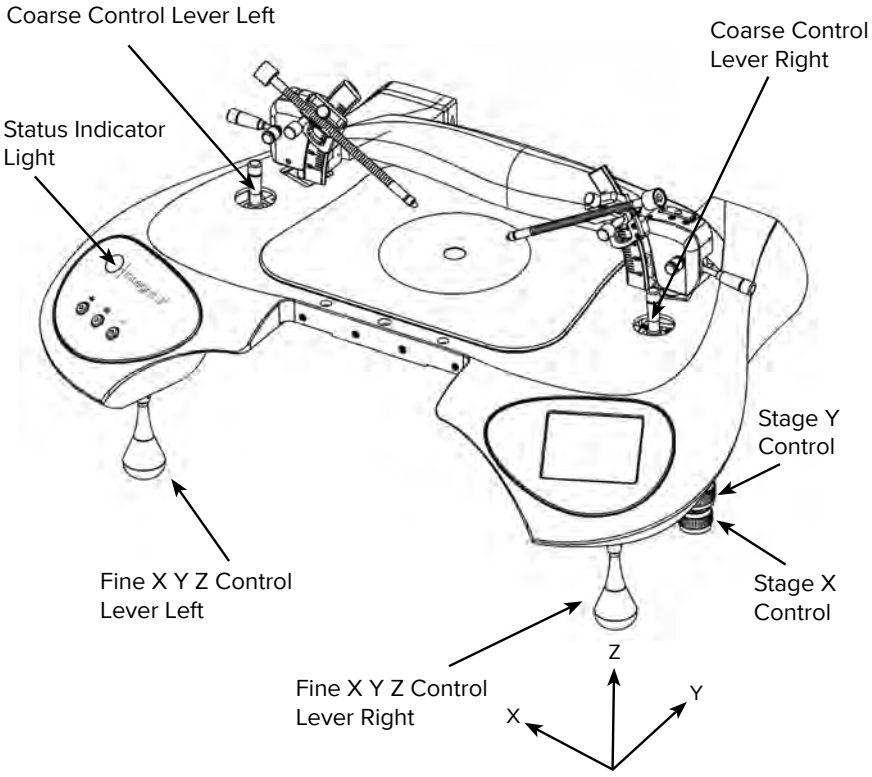


Figure 5-1

Switch on the power at the rear right hand side. The display will light up and the indicated temperature of the heating systems will start to rise. The system should not be used until the Status Indicator Light shows a continuously illuminated green light. This indicates that the temperature has settled. Refer to the 'Alarms and System Status' section for a full definition of each Status Indicator Light colour.

The operator should be positioned in such a place to easily access the microscope and also view the image on the PC monitor (where used).

The Coarse Control Lever moves the end of the micropipette through a maximum of 4mm in the x-y plane for coarse positioning of the pipette. The Fine Control Lever moves the pipette through a maximum of 0.75mm in the x and y planes, and is used for accurate positioning of tools and specimens for all normal procedures.

On each control the movement of the pipette exactly follows the movement of the control lever. So, for example, moving a lever to the left will move the pipette to the left.

The Fine Control Lever also provides Z movement of up to 5mm by the rotation of the lever.

Petri Dish Positioning

Stage movement is controlled by the X and Y controls as described on the previous page. The stage will move a maximum of 40mm in each direction ie 20mm from the centre position. This allows viewing of a specimen within the area of a Petri dish that is accessible to micropipettes.

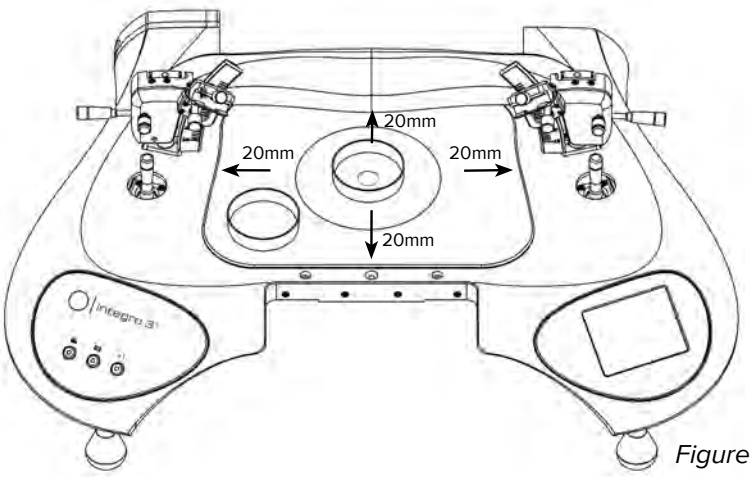


Figure 5-2

Petri Dish Choice

For most applications, we recommend plastic Petri dishes that are certified for use in ART clinics, which have a diameter of 50 to 60mm. A dish with a low wall height may be preferable to allow the maximum area of the dish to be accessible by the pipettes.

Cautions

> ⚠ Exercise caution when reaching for stage XY control that the Fine Control Lever is not knocked, especially when switching to the Integra 3 after using other stages that have the stage XY control in a different position.

Heated Stage Plate

The moving stage plate is heated, allowing a dish to be positioned away from the centre of the stage should this be required.

Heated Metal Inserts

Place the Petri dish such that the area of interest is over the hole in the centre of the insert. The effective range of movement is limited by the diameter of this hole (normally 25mm). Reposition the dish by hand to view specimens that are outside the area of the hole. It may also be necessary to reposition the dish if specimens are close to the edge of the hole or if short working distance objectives are being used, as the objective might contact the insert.

Metal heated inserts are secured in position using magnets, the insert can be lifted out by pulling upwards. When lowering the insert into position ensure that the insert is rotated until the magnets re-attach the insert securely.

Heated Glass Inserts

Place the Petri dish in the centre of the insert, avoiding the frame of the glass insert (figure 5-3). Short working distance objectives might touch the insert before the specimen is brought into focus, depending on the thickness of the glass and the dimensions of the Petri dish. Dishes with a diameter larger than 60mm may need positioning by hand if the area covered by specimen preparations exceeds 40mm in diameter.

Cautions

> ⚠ The Heated Glass Insert is fragile and should be handled with care. Do not apply excessive force to the glass surface.

> ⚠ Do not place the Petri dish over the frame of the Heated Glass Insert as this area is not heated (page 22).

> ⚠ Where an ITO Heated Glass Insert is used in conjunction with a RI Saturn 3, Saturn 5 or equivalent laser ablation system, do not fire the laser with the microscope focussed on the ITO glass surface, as this may damage the ITO coating.

The following sketch shows the location of the frame of the Heated Glass Insert (the black area).

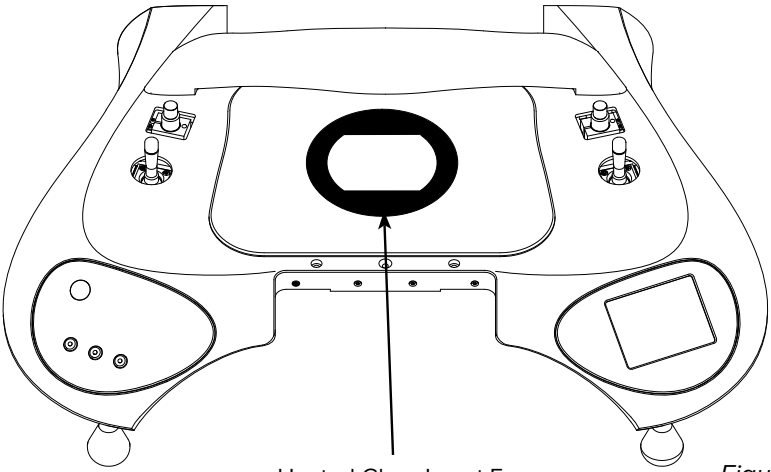


Figure 5-3

The Heated Glass Insert is secured in position using magnets. The insert can be removed by pushing gently from beneath. When lowering the insert into position ensure that the insert is rotated until the magnets re-attach the insert securely.

Fitting Micropipettes

The Integra 3 is designed to use industry standard 1.0mm diameter glass micropipettes, such as such as the Origio or TPC pipettes offered by CooperSurgical.

1. Partially unscrew the Micropipette Holder (MPH) tip.

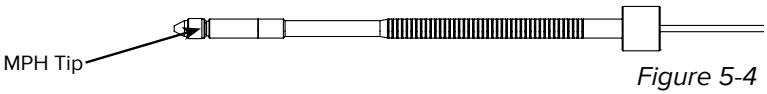


Figure 5-4

2. Remove the micropipette from the Twista Pak.

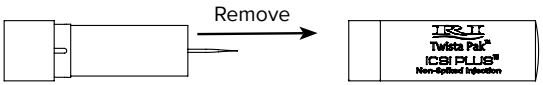


Figure 5-5

3. Insert the micropipette into the MPH tip until it passes through the O-ring and hits the stop (inside the MPH).

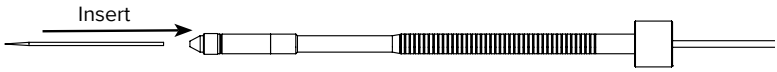


Figure 5-6

4. Tighten the MPH tip to clamp the micropipette in place.

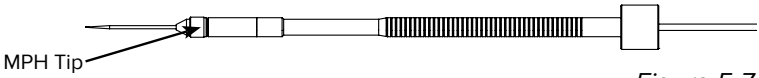


Figure 5-7

Cautions

> ⚠ High pressure can be generated in the system when using small diameter micropipettes, viscous fluids, or if a micropipette becomes blocked. This may cause micropipettes to shoot out of the holder. Release the pressure before loosening the MPH tip.

Inserting MPH into Toolholder

Raise the Set-up Lever located on the side of the toolholder and rotate the PL3 towards the front if desired. Place the narrow section of the MPH into the slot in the toolholder, then push inwards.

Initial Pipette Set-up Diagram

Note: Requires the use of two 4x objectives (one fitted with a spacer)

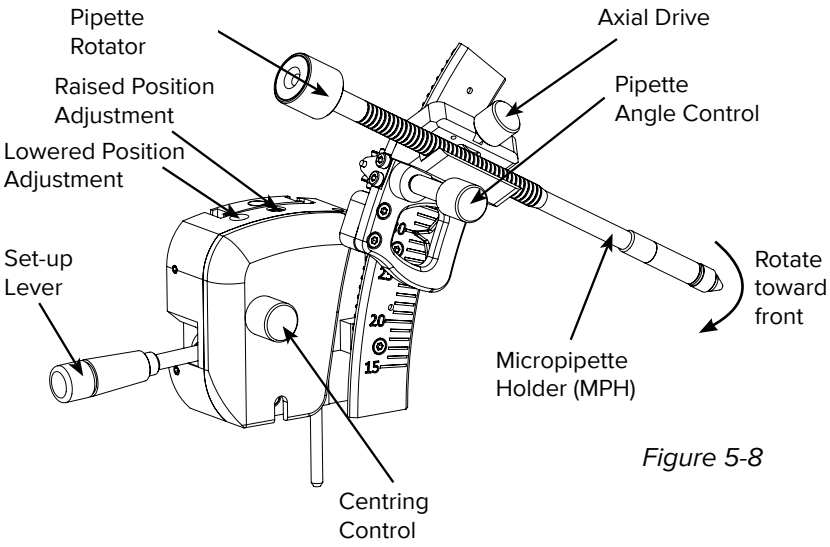


Figure 5-8

Initial Pipette Set-up Instructions

Note: Do not place any force on the baseplate as this will affect the focus.

1. Move the Fine Control (red) and Coarse Control (blue striped) Levers to a vertical position. Rotate the Fine Control Lever to the centre of the movement as indicated on the display (page 30). If the Height Indicators have not previously been calibrated this must be done first as detailed on page 30.

2. Take an empty and clean Petri dish (set-up dish), and lightly scratch a cross in its centre, on the upper surface. This must be the same type of Petri dish as used clinically.

3. Select a low magnification objective (4x without spacer). Place the Petri dish on the stage and use the microscope focus control to focus on the cross. Do not adjust the microscope focus again and do not remove the dish until the pipette set-up is complete.

4. Select the set-up objective (4x with spacer).

5. Lift the Set-up Levers to the raised position. Insert holding and injection pipettes into the MPHs and clip the MPHs into the toolholders (PL3).

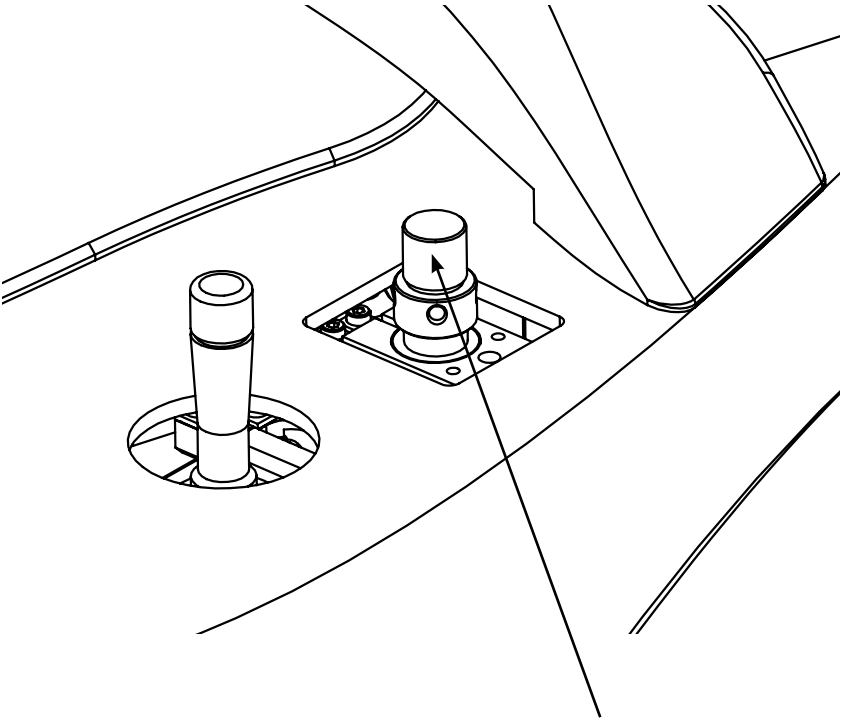
6. Adjust the angle of each pipette by turning the Pipette Angle Control.

7. Align the bend in each pipette by turning the Pipette Rotator until the toe of the pipette is in a straight line.

8. Use the Axial Drive to move the pipettes so that the tips are close to each other. Look into the eyepieces and bring the tip of each pipette to the centre of the field of view. Use the Axial Drive, if necessary, to adjust the pipette tip sideways. Use the Centring Control to move the pipette tip forwards or backwards. The tip might be out of focus - this does not matter and will be adjusted next.

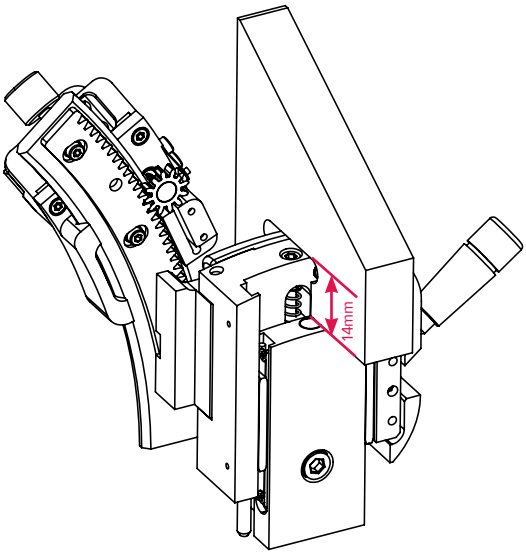
9. Turn the Raised Position Adjustment Screw on each side, not the microscope focus, to bring the pipettes into focus. Take care not to apply too much downward pressure to the screw as this may cause the PL3 to drop.

10. If the pipette cannot be brought into focus, remove the PL3 and rotate the output post to raise or lower the PL3. If necessary, use a tool in the holes in the post to assist in turning it. Each turn of the post raises or lowers it by 0.5mm.



Turn clockwise to lower,
anti-clockwise to raise

11. Refit the PL3 and set the Raised Position Adjustment Screw at the centre of the range of movement using the PL3 Set-up Tool (or measure a height of 14mm). Hold the tool as shown, just to the side of the Raised Position Adjustment Screw. Adjust the screw until it just touches at the top and bottom of the square cut-out.



12. Repeat from Step 9. Move to Step 13 when the pipette can be brought into focus with the Raised Position Adjustment Screw.

13. Select the low magnification objective without spacer. The scratch on the Petri dish should still be in focus.

14. Lower the Set-up Levers fully. The pipettes should come into view slightly above the Petri dish surface. If the pipette is too high or too low, turn the Lowered Position Adjustment Screw, **not the microscope focus,** to bring the tip of the pipette just above the Petri dish surface.

Pipette Angle Adjustment

Turn the Pipette Angle Control to increase or decrease the angle of the pipette. The tip of the pipette will stay in focus, so the angle can be changed at any time during a procedure. For example, the pipette can be set 'toe down' for sperm immobilisation and then straight for injection.

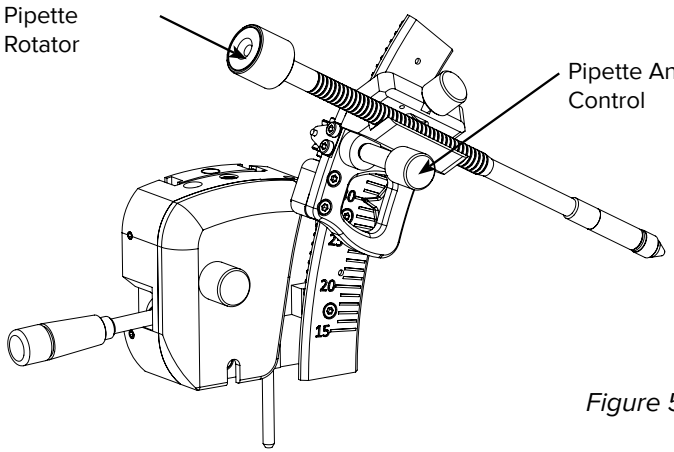


Figure 5-9

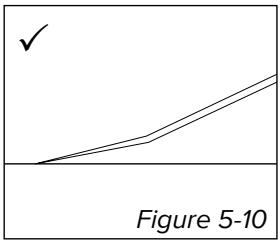


Figure 5-10

Pipette with toe down is correct for sperm immobilisation

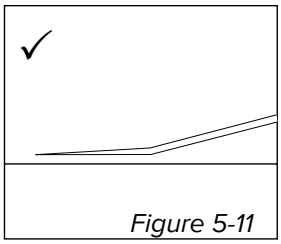


Figure 5-11

Straight pipette is correct for sperm injection

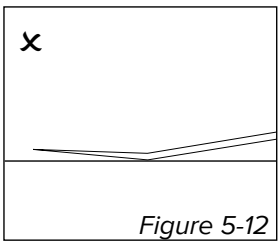


Figure 5-12

Pipette with heel down is incorrect for all procedures

Routine Pipette Set-up

Note: Do not place any force on the baseplate as this will affect the focus. If any step cannot be completed (for example, if the pipette tip is a long way out of focus at step 7), then carry out the initial pipette set-up procedure as described on the previous pages.

1. Move the Fine (red) and Coarse (blue striped) Levers to a vertical position. Rotate the Fine Control Lever to the centre of the movement as indicated on the display.
2. Take an empty and clean Petri dish (set-up dish), and lightly scratch a cross in its centre, on the upper surface. This must be the same type of Petri dish as used clinically.
3. Select a low magnification objective. Place the Petri dish on the stage and use the microscope focus control to focus on the cross. Do not adjust the microscope focus again and do not remove the Petri dish until pipette set-up is complete.
4. Select the set-up objective (4x with spacer).
5. Lift the Set-up Levers (yellow striped) to the raised position. Insert holding and injection pipettes into the Micropipette Holders (MPH) and clip the MPHs into the toolholders (PL3).
6. Adjust the angle of each pipette, if required, by turning the Pipette Angle Control.
7. Look into the eyepieces and bring the tip of each pipette to the centre of the field of view by using the Axial Drive Control (black). If the tip is out of focus, rotate the Fine Control Lever slightly (not the microscope focus) to bring it into focus.
8. Align the foot of the pipette by turning the rotator on the end of the MPH. It is horizontal when the pipette appears straight and horizontal in the eyepieces.
9. Select the low magnification objective without spacer. The scratch on the Petri dish should still be in focus.
10. Remove the set-up dish and replace with your clinical dish. Lower the Set-up Levers fully. The pipette will come into view slightly above the Petri dish surface. Small height adjustments can be made by rotating the Fine Control Lever. If the pipettes are consistently too high or too low then carry out the initial pipette set-up procedure.

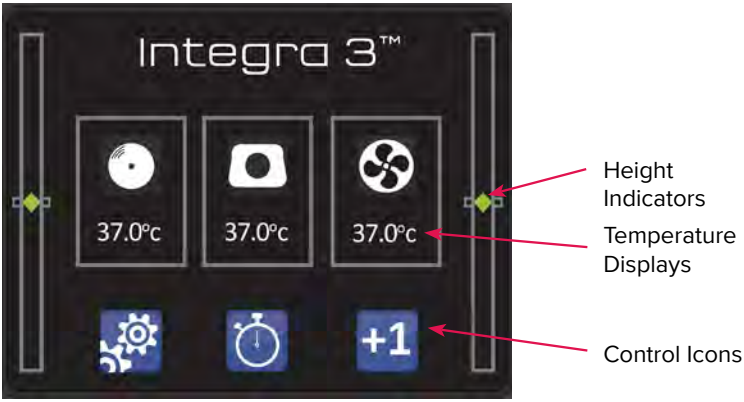
Shut Down Procedure

1. Close RI Viewer software (where used).
2. Switch off at rear.

SECTION 6 - ELECTRONIC CONTROL SYSTEM

Display

When the Integra 3 is switched on, a white screen with the RI logo is shown for a few seconds, then the main screen is shown. See User Interface Icons on page 31 for an explanation of all the icons.



Temperature displays: these show the actual temperature of each heated area. Touch the icons to adjust the setpoint temperature of each.

Control icons: touch these to access settings, calibration and other features.

Height Indicators: see Height Indicators on page 33.

User Interface Icons

The following table explains the meaning of all the user interface icons required to use and adjust the Integra 3 settings and features. The icons are referred to throughout this manual by their 'Meaning' in **Bold** typeface. eg  is referred to as the **Height Indicator Sound** icon.

Icon	Meaning	Icon	Meaning
	Height Indicator Sound		Under-stage Lights
	Audio Alarm		Increase and Decrease
	Audio Alarm Off		Yes
	Heated Metal Insert		No
	Heated Glass Insert		Service Menu*
	Thermosafe		Save
	Heated Stage Plate		Back
	System Information		Calibrate Temperature Sensor
	Stopwatch		Settings
	Start Stopwatch		Set Maximum Height (TDU)
	Pause Stopwatch		Set Centre Height (TDU)
	Stop Stopwatch		Set Minimum Height (TDU)
	Reset Stopwatch		Low Priority Alarm
+1	Counter		Medium Priority Alarm
	Event Log	CLEAR LOG	Clear Event Log

* Please note that the Service Menu should only be accessed by service personnel.

Shortcut Buttons

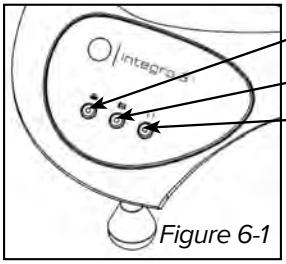


Figure 6-1

Start Video Recording**

Capture Still Image**

+1 Increment Counter

**Requires RI Viewer or RI Witness Software (optional), see the User Manual supplied with your software.

Please refer to the User Interface Icons table on the previous page for images of the icons discussed below. The icons are identifiable in the following text by their **Bold** typeface.

Stopwatch

The stopwatch can be accessed from the main screen by pressing the **Stopwatch** icon. Once in the stopwatch screen the timer can be started and stopped by pressing the **Start** and **Stop** icons respectively, and can be used between 0 and 59 minutes 59 seconds. After this time it continues timing from 0 seconds. The **Reset** icon can be used to zero the time. Press the **Back** icon to return to the main screen.

Counter

The counter can be accessed from the main screen by pressing the **Counter** icon or the +1 button on the left hand side of the Integra 3. The counter can be used to count incrementally either upwards or downwards between 0 and 99. To count upwards, press either the +1 button or press the **Increase** icon on the touch screen. To count downwards, press the **Decrease** icon on the touch screen. To reset the counter, press the **Reset** icon on the touch screen. Press the **Back** icon to return to the main screen.

Under-stage Lights

In order to improve visibility underneath the Integra 3, the device is fitted with white LED lights. These are activated by movement beneath the Integra 3. The length of time the lights remain on after detecting motion can be adjusted as follows.

Press the **Settings** icon and then the **Under-stage Lights** icon. The time period can be adjusted between 0 and 9 seconds by pressing the **Increase** and **Decrease** icons before pressing **Save** to exit. When set to 0 seconds the lights will remain off. Press the **Back** icon to return to the main screen.

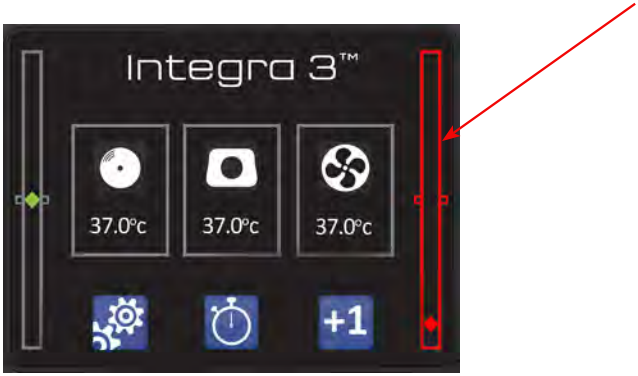
Height Indicators

These show the vertical position of the toolholders, as set by rotating the Fine Control Levers. If the Fine Control is turned close to the ends of the range of movement, the display will turn red and the Integra 3 will emit three short beeps, repeating every 5 seconds.

When commencing a procedure the TDU vertical position should be close to the centre of their range of movement. If the TDU needs to be set away from the centre point in order to bring the pipette into focus then follow the Initial Pipette Set-up Instructions on page 24 before proceeding.

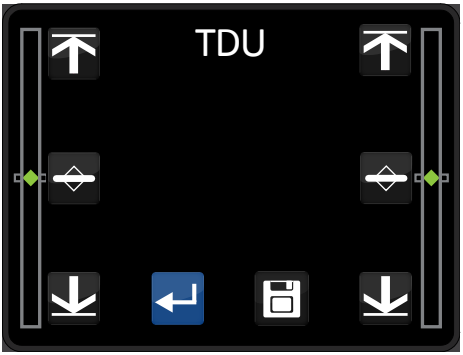
Cautions

⚠ Avoid using the system in the position pictured below, as there may be insufficient movement to complete the procedure.



Height Indicator Calibration

The Height Indicators are factory calibrated. However, they can be recalibrated as required. If resistance is felt when turning the Fine Control Lever before the Height Indicator shows that the limit of movement has been reached then re-calibration is required.



Touch the **Settings** and then the **Calibrate Height Sensor** icon.

For each side in turn, rotate the Fine Control Lever fully to the bottom of the range of movement. Touch the **Set Minimum Height** icon. Rotate the Fine Control to the top of the range of movement and touch the **Set Maximum Height icon**. Next rotate the Fine Control Lever 11 complete turns downwards. It may help to put a pencil mark or small piece of tape on the lever to count the turns. Now touch the **Set Centre Height** icon. Touch the **Save** icon to save the calibration, then the **Back** icon to return to the main screen. **Note:** If the **Back** icon is touched without saving then any changes to the calibration will not be saved and it will revert to the previous calibration.

System Information

In order to provide additional information in the event of a fault, the System Information screen can be accessed from main screen by pressing the **Settings** and then the **Information** icon. This screen is for information only and it is not possible to change any values from this screen. Press the **Back** icon to return to the main screen.

The following abbreviations are used to identify parameters given on the System Information screen:

Abbreviation	Description	Abbreviation	Description
TP	Instantaneous Temperature (°C)	**AR**	Air Flow
SP	Temperature Setpoint (°C)	**AS**	Air Flow Setpoint
CL	Calibration Value (°C)	**SN**	Serial Number
PW	Heating Power (%)	**FW**	Firmware Version
FS	Fan Speed (%)	**HW**	Hardware Version

SECTION 7 - TEMPERATURE CONTROL

Cautions

> ⚠ To ensure embryo safety, the temperature setpoint should be set to maintain the specimen at the correct temperature. See 'Adjusting Specimen Temperature'.

> ⚠ In the event of a temperature sensor malfunction, the setpoint temperature may be exceeded and the surface may become hot to the touch. It is recommended that temperatures are checked on a regular basis.

When Integra 3 is powered up, the display briefly shows RI and the product logo. After start up the screen shows the actual temperatures of the devices connected. **Note:** The heating systems are continually monitored for safe operation.

Various heating options are available for the Integra 3.
A brief description and how to identify each option is detailed below.
Refer to the Integra 3 Installation and Service Manual (6-54-701IM) for further information about changing the heating option (mode).

Heated Stage Plate and Heated Metal Insert (Mode 1)

The Heated Stage Plate and, when fitted, the Heated Metal Insert are shown on the main screen. The setpoint of each can be changed individually, however, in practice the setpoint of each will normally be set to a similar value.

Heated Stage Plate and Heated Glass Insert (Mode 2)

The Heated Stage Plate and when fitted, the Heated Glass Insert are shown on the main screen. The setpoint of each can be changed individually. In practice the setpoint temperature of the Heated Glass Insert will normally be set slightly higher than the Heated Metal Stage.

Heated Stage Plate and Heated Metal Insert with Thermosafe (Mode 3)

The Heated Stage Plate and Heated Metal Insert can be used with the Thermosafe Air Heating System. The setpoint of each can be changed individually, however in practice the setpoint of each will normally be set to a similar value.

Heated Stage Plate Only (Modes 4 and 5)

The Integra 3 can be configured to operate only the Heated Stage Plate. This is typically only required when using the Integra 3 with an externally controlled stage insert not manufactured by RI.

When using an externally controlled heating stage insert Mode 4 enables the Heated Stage Plate setpoint temperature to be adjusted between 30 and 45°C.

When using an externally controlled heating/cooling stage insert, Mode 5 enables the Heated Stage Plate setpoint temperature to be adjusted between 30 and 45°C or switched off.

Thermosafe

The Thermosafe Air Heating System passes a steady stream of warm air across the central hole of a Heated Metal Insert. Air passes through a filter, fan and heater before exiting from the nozzle located close to the central hole of the Heated Metal Insert.

Note: It is normal for the air heater enclosure to become warm when in use.

The temperature of air exiting the nozzle is controlled to a high degree of accuracy, with the quantity of air preset to an optimum value to give the most consistent heating across the central hole of the metal insert. As with most microscope based heating systems, sample temperature will be affected slightly by ambient conditions.

The system has been designed to not interfere with the normal operation of the manipulation system. Consequently, all components of this system are located underneath the baseplate, with the exception of the filter which is located at the rear of the baseplate for ease of access.

Caution

⚠ The Thermosafe Air Heating System has been designed to minimise audible noise and vibration, which should not be noticeable under normal operating conditions. In the event of audible noise or vibration from the system, contact RI for support.

Refer to the Care and Maintenance section for requirements to change the Thermosafe Air Heating System filter (Figure 11-2 on page 70).

Setting the Temperature

Caution

> ⚠ Do not adjust the temperature with a specimen in place on the heated surface.

The setpoint temperature of each heating system can be modified by pressing the icons mentioned on page 35, which are located on the main screen. The value is modified by pressing the **Increase** or **Decrease** icons. Once the correct value is obtained, press the **Save** icon to return to the main screen.

When using the Heated Stage Plate only with an externally controlled heating/cooling insert (Mode 5), an additional option on the setpoint screen enables the Heated Stage Plate to be switched off. In this case the display will show 'HEATING OFF' when on the main screen.

Note: It may take up to 20 minutes for the temperature to stabilise. In all cases an alarm will sound if the setpoint temperatures are not reached. Refer to the Alarm and System Status section for a full description of alarms.

Adjusting Specimen (Setpoint) Temperature

The heating systems are factory calibrated such that when the controller is set to 37°C the surface temperature of the heated plate(s) and air expelled from the Air Heating System (if fitted) measures 37°C. For all heating systems the setpoint temperature is adjustable to between 30°C and 45°C.

The temperature inside a Petri dish will normally be slightly lower than the heated surface, depending on ambient conditions, type of Petri dish and the sample preparation. After the system has been installed in its operating location, the temperature of the heated plate(s) and Thermosafe Air Heating System (if fitted) should be adjusted to allow for this difference.

Change the setpoint if the temperature in the Petri dish needs to be changed. For example, the heated plate might need to be set to 41°C in order for the specimen to be at 37°C.

Prepare a Petri dish with water and paraffin oil that mimics your normal Petri dish preparation and place it on the heated stage in its normal position.

Where the Thermosafe Air Heating System is fitted, it is recommended that temperature measurements are made above the centre of the objective **and** over the heated plate (see Figure 7-1 on page 38).

For optimum temperature control across the hole in the heated plate, adjust the setpoint temperature of the Thermosafe Air Heating System. To control the area directly above the heated plate, adjust the heated plate setpoint temperature. As a starting point, use the same setpoint temperature for both heating systems.

In all cases, it is recommended that the objective normally used for manipulation is in position when measuring specimen temperature and adjusting setpoint temperatures.

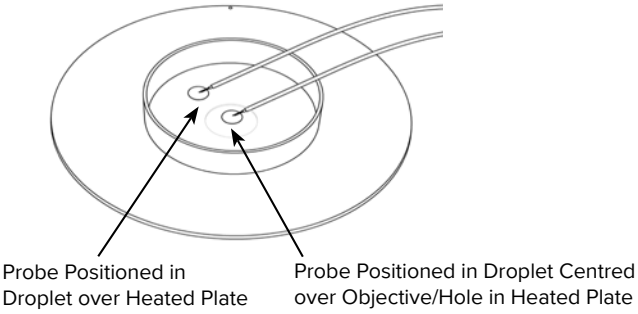


Figure 7-1

We recommend using a thermometer calibrated to 37°C fitted with a small thermocouple probe, such as the RI IVF Thermometer. Place the probe of the thermometer in the centre of the water drop and allow the temperature reading to stabilise. Adjust the setpoint temperature until the desired temperature in the dish is reached, allowing 20 minutes (or as long as required) in between each setpoint change to allow the Petri dish temperatures to stabilise.

Temperature Calibration

Perform calibration only if the displayed temperature is different to the actual temperature of the heated plate surface or the air expelled from the air heater nozzle. The process of calibration allows the user to manually adjust the temperature so that the displayed temperatures match the temperature of the heated plate or air expelled from the air heater nozzle.

Temperature calibration can be performed on each of the heating options listed at the start of the Temperature Control section. The calibration screen is accessed by pressing the **Settings** icon on the main screen, then the **Calibrate Sensor** icon.

The displayed temperature is adjusted using the **Increase** or **Decrease** icons until the value matches that of the thermometer used to perform the calibration. Following calibration and after returning to the main screen, it is advisable to leave the probe in position for a short while in order to verify that temperatures are as expected. The recommended method of calibration is described below.

Caution

⚠ Repeat procedure for Adjusting Specimen (Setpoint) Temperature after performing calibration.

Calibrating Heated Plates

Place the probe of a calibrated thermometer in good thermal contact with the surface. **Note:** Simply touching the probe on the surface is not adequate. Use a purpose-made surface probe or use thermal transfer paste. Products sold for computer heatsinks are suitable, and RI can also supply suitable materials.

Note: When the system is fitted with the Heated Stage Plate and Heated Metal Insert, these must be calibrated independently.

After switching on, **wait at least 20 minutes** to allow the temperature to stabilise before calibrating.

Recommended positions for temperature measurement during calibration of heated plates are shown below for both metal (Figure 7-2) and glass (Figure 7-3) heated stage options.

Heated Metal Insert

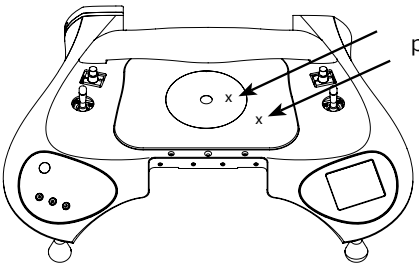


Figure 7-2

Heated Glass Insert

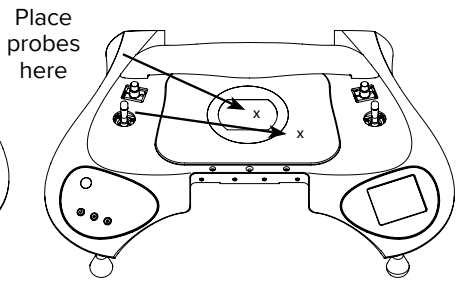


Figure 7-3

Note: For the Heated Glass Insert, it is not recommended that temperatures are measured directly above the objective during calibration. This is because the objective cools that part of the plate. Either move the objective away from the glass or measure slightly to the side of the objective as shown (Figure 7-3).

Calibrating Thermosafe Air Heating System

Access to the air nozzle from above will be improved by lifting out the Metal Heated Insert and moving to one side.

7

Place the probe of a calibrated thermometer through the small hole on the side of the air nozzle (see Figure 7-4) until the probe tip is centralised in the air stream.

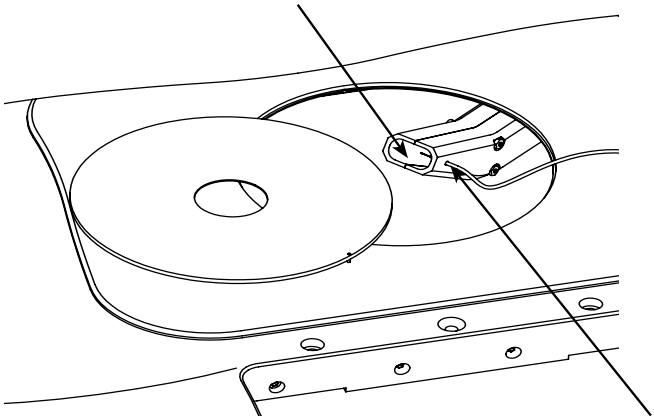


Figure 7-4

After switching on, wait at least 20 minutes to allow the temperature to stabilise before calibrating.

SECTION 8 - ALARMS AND SYSTEM STATUS

The status of the temperature control system is shown by the Status Indicator Light on the left hand side of the Integra 3. Individual temperatures are shown on the touch screen display.

Status Indicator Light

Off - Please wait (Initial power up/setpoint/mode/calibration changed) light will be off until temperature of all heating systems is within ±0.5°C of setpoint.

Green (constantly on) - Ready for use. Temperature of all heating systems within ±0.5°C of setpoint.

Yellow (constantly on) - Low Priority Alarm. Press the **Event Log** icon shown on the main screen to view specific alarm conditions.

Yellow (flashing) - Medium Priority Alarm. Press the **Event Log** icon shown on the main screen to view specific alarm conditions.

When multiple alarms are active, the icon and Status Indicator Light for the highest priority alarm will be shown.

Note: For a full list of possible faults relating to each alarm condition and applicability of each alarm condition, refer to the Troubleshooting section of this manual.

Once activated, all alarms are sounded immediately as the alarm condition occurs.

Audible Alarms

Audible alarms are sounded to indicate Low and Medium Priority Alarms, as described above. When an alarm is sounding, the alarm can be muted by pressing the **Audio Alarm Off** icon which appears on the display (alarm audio is automatically unmuted each time a new alarm becomes active). When multiple alarms are active, the audio for the highest priority alarm will be sounded. The alarm volume is not adjustable. Low and medium priority alarms are sounded at the same level (this is a higher level than other available indications used by the Integra 3). Sound levels for the alarm system are as follows:

Priority	Range	Average
Medium Priority	52.6 - 63.9dB	61.9dB(A)
Low Priority	54.3 - 65.1dB	63.4dB(A)

In addition to the alarms listed above, sounds are emitted to indicate touch screen key presses and when the toolholders are reaching the limits of their vertical adjustment.

Alarm System Testing

In order to test functionality of the alarm system, allow the system temperatures to stabilize (Status Indicator Light shows a continuously illuminated green light). Then place a cold object (eg a glass beaker of cold tap water, or a metal block) onto the Heated Stage Insert or Heated Stage Plate. Observe the temperature of the Heated Stage Insert or Heated Stage Plate channel on the main screen. Once the temperature deviates more than ±0.5°C from the setpoint temperature verify that a medium priority alarm signal is emitted (3 audible pulses and 3 yellow flashes of the Status Indicator Light). This check should be performed at regular intervals to reduce the chance of missing an alarm due to failed loudspeaker or Status Indicator Light.

Event Log

When alarms are sounded an entry is made in the internal Event Log. Each alarm or event recorded is tagged with the elapsed time. The Event Log displays the last 5 events. This is accessible by pressing the **Settings** icon on the main screen, then **Event Log** or by pressing the **Event Log** icon which appears on the main screen after an alarm has sounded. The **Event Log** icon will be present on the main screen until the log has been cleared by pressing the **Clear Event Log** icon or until Integra 3 is powered off.

SECTION 9 - SYRINGES

Warnings

Warning: High pressure can be generated in the system when using small diameter micropipettes, viscous fluids, or if a micropipette becomes blocked. This may cause micropipettes to shoot out of the holder. Before releasing the pipette from its holder, release the pressure in the syringe by pressing the release button on the top.

To minimise the risk of injury:

- Never point the pipette towards yourself or anyone else
- Always make sure the pipette is securely mounted in the holder before use
- Release the pressure before loosening the micropipette tip
- When removing a pipette from the holder, be sure to hold the pipette between your fingers as the holder tip is loosened
- A self-adhesive warning label is supplied, which should be placed in a prominent position as close as possible to the device when in use

A self-adhesive warning label is supplied, which should be placed in a prominent position as close as possible to the device when in use.

Cautions

Caution: The syringes should be operated by qualified and trained personnel only.

For ICSI in the USA

Caution: US Federal Law restricts this device for sale to or on order of a physician. This device is intended for use for Intra Cytoplasmic Spermatozoa Injection (ICSI). All other uses must be for investigational purposes or in the research laboratory only.

SAS - Screw-Actuated Air Syringe Assembly

Note: Do not fill the syringe or tubing with oil

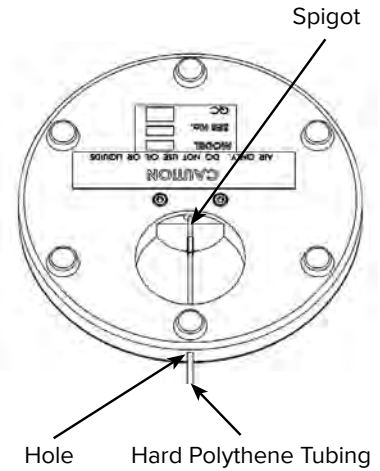


Figure 9-1

1. Turn the unit upside down.
2. Insert the end of the hard polythene tubing through the hole in the side of the base.
3. Ease the tubing over the spigot, ensuring that the tubing is securely fitted.
4. The other end of the tubing is fitted to the micropipette holder.

SAS & SAS-SE Specification Table

Description	SAS™	SAS-SE™
Piston Stroke	23mm	30mm
Weight	1.4kg	1.7kg
Overall Dimensions	125mm diameter x 95mm high	125mm diameter x 120mm high

SAS Operation

Suction/Injection is obtained by turning the rotator on top of the syringe.

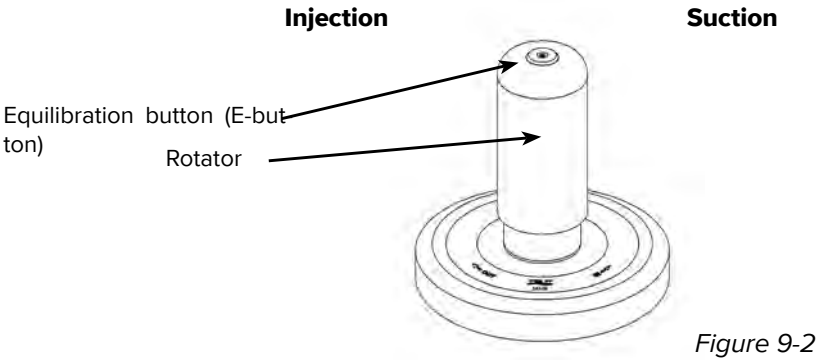


Figure 9-2

> ⚠ High pressure can be generated in the system when using small diameter micropipettes, viscous fluids, or if a micropipette becomes blocked. This may cause micropipettes to shoot out of the holder. Press the E-button to release the pressure before loosening the micropipette holder tip to remove a micropipette.

Notes on SAS

If the sperm is moving in or out of the pipette too quickly, either the equilibration is not complete or the rotator has been turned too far.

The E-button releases the internal air pressure when pressed. Capillary action will cause the PVP/medium to move up the pipette. This can be countered with a small clockwise movement of the rotator to balance the pressure.

Equilibration Procedure

This procedure balances the pressure in the syringe with the capillary action of the pipette, allowing the most accurate control of the sperm injection.

The following is a typical procedure. However, other methods are possible, eg using medium without PVP. Individual clinics may develop their own procedures.

Injection pipette: Equilibrate with PVP

Holding pipette: Equilibrate with medium

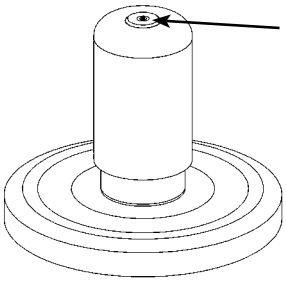


Figure 9-3

1. Place a drop of PVP/medium in the centre of a Petri dish.
2. Ensure the rotator is at the lower end of the movement. Turn the rotator down (clockwise), if necessary.
3. Press the E-button (equilibrating button).
4. Using the toolholder set-up lever, lower the micropipette into the drop.
5. Rotate the SAS anti-clockwise (ie upwards) 5 to 6 turns for an injection pipette, or 1 turn for a holding pipette. Do not allow the PVP/medium to enter the tubing. The level of the PVP/medium should always be clearly visible inside the pipette.
6. Press the E-button.
7. Leave to equilibrate for 1-2 minutes.

SOS - Screw-Actuated Oil Syringe Overview

The SOS is a screw actuated syringe for the precise transfer and injection of spermatozoa. By using oil (which has very low compressibility) to transfer the movement of the control knob to the specimen, accurate aspiration and injection can be easily achieved.

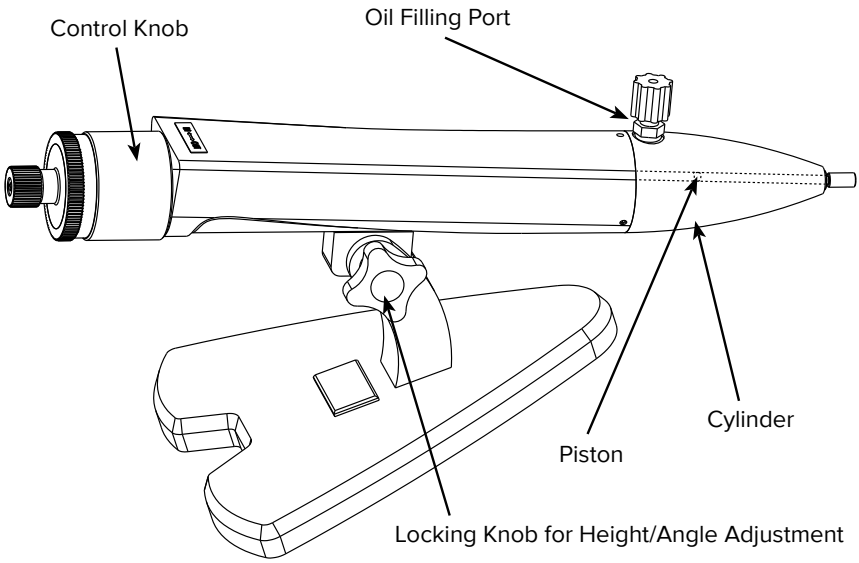


Figure 9-4

SOS Specification Table

Description	Measurement
Piston Stroke	50mm
Maximum Distance Volume	830µl
Volume Displaced Per Turn	8.3µl
Total Fill Volume (including tubing)	Approx. 2ml
Weight	1.5kg
Overall Dimensions	260 x 135 x 110mm

Fitting Tubing to a SOS

Use hard polythene tubing as supplied by RI. Use of soft tubing will result in poor specimen control.

1. Slide the nut over the tubing.
   Note: The non-threaded end should be pushed over first.

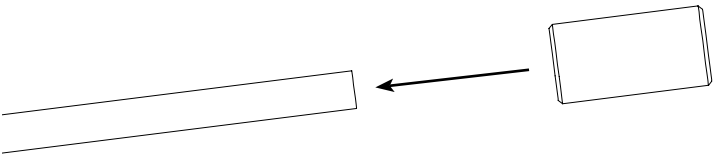
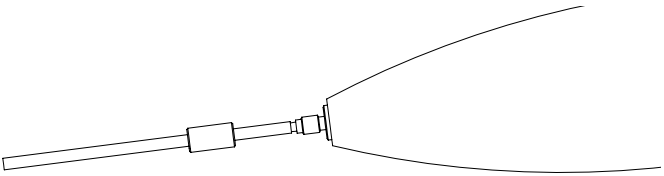
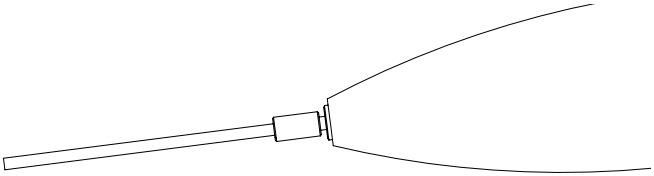


Figure 9-5

2. Push the end of the tubing firmly onto the tip of the fitting.



3. Tighten the nut onto the fitting. Use only finger pressure. *Figure 9-6*



4. Fit the other end of the tubing to the Micropipette Holder.

Figure 9-7

Figure 9-8

Filling a SOS with Oil

RI recommends sterile filtered paraffin oil.

Syringes and caps must be screwed ontothe fill port with gentle finger pressure only. Overtightening may damage the fittings.

1. Stand the SOS on its end as shown below. Fill the syringe supplied with oil, unscrew the cap from the fill port and screw the syringe Oil Filling Port.

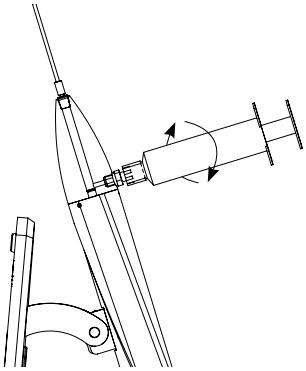


Figure 9-9

2. Press the syringe plunger slowly until the level of oil in the cylinder is just below the tip. Look closely for any air bubbles in the oil. Any that are seen can be dislodged by a short, sharp movement of the filling syringe and should be allowed to rise to the top of the oil.

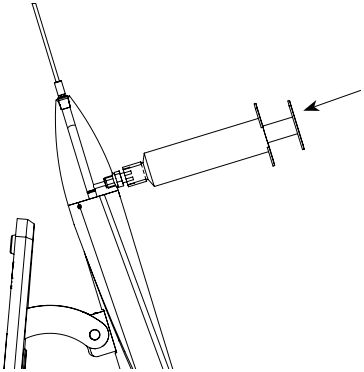


Figure 9-10

3. When you are certain there are no air bubbles, continue pressing the syringe plunger to fill the cylinder and the tubing until a small amount of oil emerges from the tip of the Micropipette Holder.

4. Turn the SOS to a horizontal position. Add a few drops of oil to the fill port until the oil is level with the top of the port.

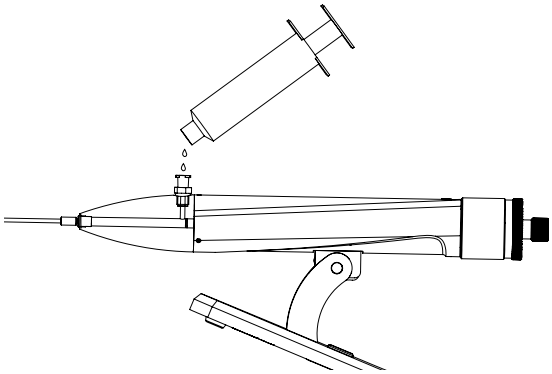


Figure 9-11

5. Refit the cap ensuring that no air bubbles are trapped underneath. A small amount of oil may be spilled, which should be wiped away with an absorbent paper towel.

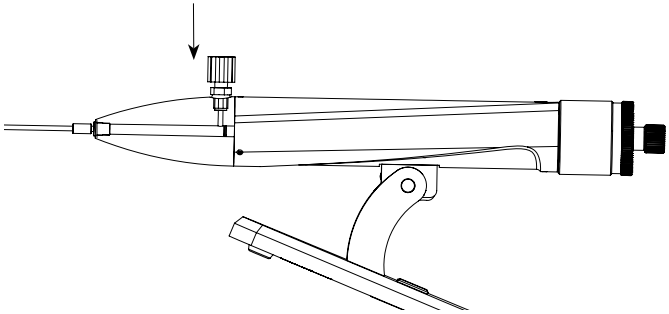


Figure 9-12

6. With each procedure the operating position of the plunger will move further towards the tip of the SOS. When the plunger is close to the tip as shown, the system should be topped up with oil.

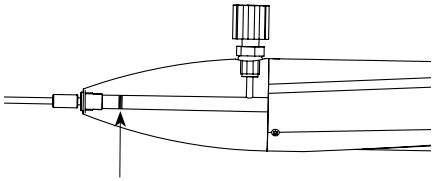


Figure 9-13

7. Stand the SOS on end as shown below. Turn the Control knob to move the plunger below the fill port. Remove the cap from the fill port. Fill the syringe with oil ensuring that there are no air bubbles in the syringe.

10.

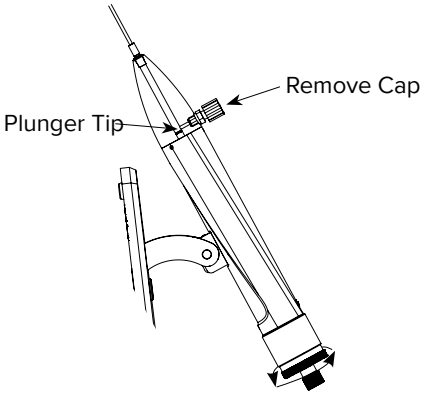


Figure 9-14

8. Add a few drops of oil to the fill port and insert the syringe ensuring that no air bubbles are trapped. If an air bubble is seen then reattach the syringe or expel the bubble into the cylinder and allow it to rise to the top before continuing

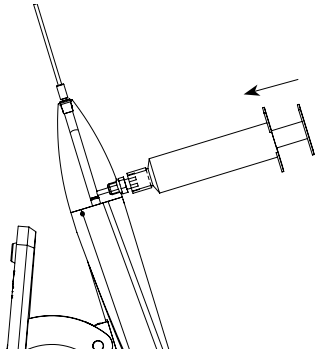


Figure 9-15

9. Now press the syringe plunger slowly to fill the cylinder and the tubing. Next fill the port and replace the cap (see Figure 9-11 and Figure 9-12 on page 50).

Fitting a Pipette

1. Hold the pipette holder vertically and turn the Control Knob clockwise until a drop of oil emerges from the tip. Slide the pipette into the holder and tighten the tip.

2. Part fill the pipette with oil by turning the SOS Control Knob, but make sure there is an air bubble between the oil and the media. This avoids contact between the oil and the media reducing the risk of contamination.

Using a SOS

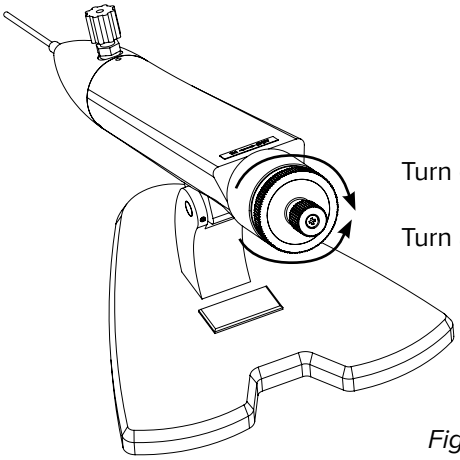


Figure 9-16

SECTION 10 - TROUBLESHOOTING

For any issues not covered below, please contact your distributor or the RI service team directly.

Manipulation

Problem	Possible cause	Solution
The stiffness of the Fine Control Lever is too tight or too loose	Lever stiffness not adjusted	Select the green-ended hexagon driver from the tool kit provided. Loosen the locking screw, then adjust the lever's resistance by turning anti-clockwise to loosen or clockwise to tighten.* (See Figure 10-1)
The stiffness of the Coarse Control Lever is too tight or too loose	Lever stiffness not adjusted	Select the green-ended hexagon driver from the tool kit provided. Insert the driver into a screw head located around the Coarse Control Lever and slightly tighten or loosen the screw (less than one turn). Test the lever action. If it is not to your liking, insert the driver into a different screw head and loosen or tighten. ** (See Figure 10-2)

* When adjusting the resistance, turn the adjuster by the smallest possible amount. If any problems occur contact the RI service team.
** The screw must not be too loose or lost motion will be introduced.

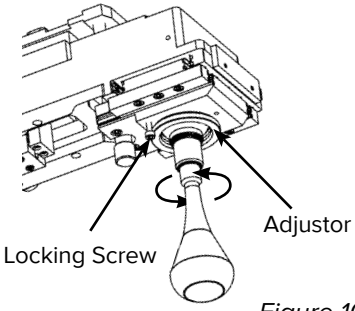


Figure 10-1

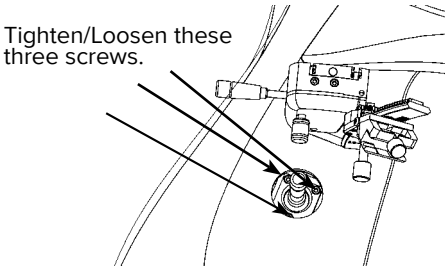


Figure 10-2

Problem	Possible Cause	Solution
Objectives hit Heated Stage Insert when changing objectives or adjusting focus	Objectives are focused too high	Refocus on the top surface of a Petri dish
	The specimen is too close to the edge of the hole in the insert, causing the objective to foul the side of the hole	Position the specimen as close as possible to the centre of the hole in the insert
	Short working distance objective fitted	Please contact CooperSurgical for more information

Temperature Controller

Problem	Possible cause	Solution
Heated Stage Insert or Heated Stage Plate too hot or too cold	Insufficient settling time	After switching on the system should be left for the display to show a constant temperature before use
	Difference in temperature between specimen and plate surface	Adjust the setpoint to allow for the difference (see page 37)
	Temperature setpoint incorrect	Touch the screen on the icon corresponding to the affected heating system. Change if necessary then press **Save**

Alarm Code Tables

The following tables on pages 52 to 62 lists Alarm Condition Code numbers, displayed Error Message, Priority, Fault Description, Alarm Actions and a Solution to the fault.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E01	HEATED STAGE HEATING FAILURE	Low	Heated Stage Plate or Thermosafe Air Heating System is not able to heat. Alarm activated 2 minutes after power on if there is less than 1.0°C temperature rise between 1 and 2 minutes after power on. If the temperature at 1 minute is already within ±2.5°C from the setpoint the test is omitted.	Heated Stage Plate controller power is set to 0% until the Integra 3 is re-started.	Switch off the Integra 3 and verify that the Heated Stage Plate cables and connector are secure and undamaged. Possible heater or controller fault.
E02	THERMOSAFE HEATING FAILURE	Low		Thermosafe Air Heating System controller power is set to 0% and fan speed is set to 0% until the Integra 3 is re-started.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connectors are secure and undamaged. Possible heater or controller fault.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E03	HEATED INSERT HEATING FAILURE	Low	Heated Stage Insert is not able to heat. Alarm activated 2 minutes after power on if there is less than 1.0°C temperature rise between 1 and 2 minutes after power on. If the temperature at 1 minute is already within ±2.5°C from the setpoint the test is omitted.	Heated Stage Insert controller power is set to 0% until the Integra 3 is re-started.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.
E04	HEATED STAGE SENSOR FAILURE	Low / Medium*	No signal/out of range signal from Heated Stage Plate or Thermosafe air temperature sensor. Alarm activates at any time if the temperature sensor circuit fails to read a valid temperature.	Temperature is shown as -.-°C. Heated Stage Plate controller power is set to 0% until a valid temperature is read.	Switch off the Integra 3 and verify that the Heated Stage Plate cables and connector are secure and undamaged. Possible heater or controller fault.
E05	THERMOSAFE SENSOR FAILURE	Low / Medium*		Temperature is shown as -.-°C. Thermosafe Air Heating System controller power is set to 0% and fan speed is set to 0% until a valid temperature is read.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connectors are secure and undamaged. Possible heater or controller fault.

* Low priority is set if condition appears within the first 5 seconds from power up. Medium priority is set if condition appears after the first 5 seconds from power up.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E06	HEATED INSERT SENSOR FAILURE	Low / Medium*	No signal/out of range signal from Heated Stage Insert temperature sensor. Alarm activates at any time if the temperature sensor circuit fails to read a valid temperature.	Temperature is shown as -.-°C. Heated Stage Insert controller power is set to 0% until a valid temperature is read.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.
E07	HEATED STAGE OVER TEMPERATURE	Medium	Heated Stage Plate temperature has exceeded the maximum allowable setpoint temperature. Alarm activates at any time if the temperature sensor exceeds 46°C.	Heated Stage Plate controller power is set to 0% until temperature falls to below 46°C. Temperature is shown as -.-°C above 55°C.	Switch off the Integra 3 and verify that the Heated Stage Plate cables and connectors are secure and undamaged. Possible heater or controller fault.
E08	HEATED STAGE TEMPERATURE OUTSIDE ±2.5°C	Medium	Heated Stage Plate temperature has deviated more than 2.5°C away from the setpoint temperature. Alarm enabled 1 minutes after reaching ±2.5°C from the setpoint.	The Heated Stage Plate temperature controller continues to operate.	Switch off the Integra 3 and verify that the Heated Stage Plate cables and connectors are secure and undamaged. Possible heater or controller fault.

* Low priority is set if condition appears within the first 5 seconds from power up. Medium priority is set if condition appears after the first 5 seconds from power up.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E09	HEATED STAGE TEMPERATURE OUTSIDE ±0.5°C	Medium	Heated Stage Plate temperature has deviated by more than 0.5°C from the setpoint temperature. Alarm enabled 5 minutes after the temperature reaches ±2.5° from the setpoint temperature.	The Heated Stage Plate temperature controller continues to operate.	This may be caused by placing either hot or cold objects on the stage. In this case either remove the object or wait a short time for the setpoint temperature to reached. Sudden air movements or temperature change can also cause minor temperature fluctuations. In this case wait a short while for the temperature controller to respond. Switch off the Integra 3 and verify that the Heated Stage Plate cables and connectors are secure and undamaged. Possible heater or controller fault.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E10	THERMOSAFE OVER TEMPERATURE	Medium	Thermosafe air heater temperature has exceeded the maximum allowable setpoint temperature. Alarm activates at any time if the temperature sensor exceeds 46°C.	Thermosafe Air Heating System controller power is set to 0% until temperature falls to below 46°C. Temperature is shown as -.-°C above 55°C.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connector are secure and undamaged. Possible heater or controller fault.
E11	THERMOSAFE TEMPERATURE OUTSIDE ±2.5°C	Medium	Thermosafe Air Heating System temperature has deviated by more than 2.5°C from the setpoint temperature. Alarm enabled 1 minute after the temperature reaches ±2.5° from the setpoint temperature.	Thermosafe Air Heating System temperature controller continues to operate.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connector are secure and undamaged. Possible heater or controller fault.
E12	THERMOSAFE TEMPERATURE OUTSIDE ±0.5°C	Medium	Thermosafe Air Heating System temperature has deviated by more than 0.5°C from the setpoint temperature. Alarm enabled 5 minutes after the temperature reaches ±2.5° from the setpoint temperature.	Thermosafe Air Heating System temperature controller continues to operate.	Sudden air movements or temperature change can also cause minor fluctuations in temperature. In this case wait a short while for the temperature controller to respond.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E13	HEATED INSERT OVER TEMPERATURE	Medium	Heated Stage Insert temperature has exceeded the maximum allowable setpoint temperature. Alarm activates at any time if the temperature sensor exceeds 46°C.	Heated Stage Insert controller power is set to 0% until temperature falls to below 46°C. Temperature is shown as -.-°C above 55°C.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.
E14	HEATED INSERT TEMPERATURE OUTSIDE ±2.5°C	Medium	Heated Stage Insert temperature has deviated by more than 2.5°C away from the setpoint temperature. Alarm enabled 1 minute after the temperature reaches ±2.5° from the setpoint temperature.	The Heated Stage Insert temperature controller continues to operate.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E15	HEATED INSERT TEMPERATURE OUTSIDE ±0.5°C	Medium	Heated Stage Insert temperature has deviated by more than 0.5°C from the setpoint temperature. Alarm enabled 5 minutes after the temperature reaches ±2.5° from the setpoint temperature.	The Heated Stage Insert temperature controller continues to operate.	This may be caused by placing either hot or cold objects on the stage. In this case either remove the object or wait a short time for the setpoint temperature to reached. Sudden air movements or temperature change can also cause minor temperature fluctuations. In this case wait a short while for the temperature controller to respond. Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E16	FLOW SENSOR FAILURE	Low / Medium*	No signal/out of range signal from air flow sensor. Alarm activates at any time if the flow sensor fails to give a valid reading.	Thermosafe Air Heating System controller power is set to 0% and fan speed is set to 0% until the flow reading is valid.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connector are secure and undamaged. Possible air flow sensor, fan or controller fault.
E17	AIR FLOW FAILURE	Medium	The controller is not able to maintain the air flow rate (the air flow is outside of ±150 units from the air flow setpoint). Alarm is enabled 5 minutes after power on.	If the airflow is still outside ±150 units from the setpoint 5 minutes after the alarm has been triggered, Thermosafe Air Heating System controller power is set to 0% and fan speed should be set to 0% until the Integra 3 is re-started.	

* Low priority is set if condition appears within the first 5 seconds from power up. Medium priority is set if condition appears after the first 5 seconds from power up.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E18	THERMOSAFE OVERHEAT PROTECTION TRIGGERED	Low / Medium*	A fault has caused the Thermosafe Air Heating System's internal temperature to rise above the normal operating temperature. Alarm activates at any time.	Thermosafe Air Heating System controller power is set to 0% and fan speed is set to 0% unti the Integra 3 is re-started.	Switch off the Integra 3 and check for air flow obstructions, verify the Thermosafe filter media pad is free from dust build up. Also check that cables and connector are secure and undamaged. Possible heater, thermal switch or controller fault.
E19	HEATED INSERT LOW HEATING RATE	Medium	Heated Stage Insert was not able to achieve the setpoint temperature. Alarm activated 15 minutes after power on if the temperature is not within ±2.5°C of the setpoint temperature.	Temperature controller continues to operate.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault. Operating the Integra 3 below its ambient temperature specification may produce this alarm.

* Low priority is set if condition appears within the first 5 seconds from power up. Medium priority is set if condition appears after the first 5 seconds from power up.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E20	HEATED STAGE LOW HEATING RATE	Medium	Heated Stage Plate was not able to achieve the setpoint temperature. Alarm activated 15 minutes after power on if the temperature is not within ±2.5°C of the setpoint temperature.	Temperature controller continues to operate.	Switch off the Integra 3 and verify that the Heated Stage Plate cables and connector are secure and undamaged. Possible heater or controller fault. Operating the Integra 3 below its ambient temperature specification may produce this alarm.
E21	THERMOSAFE LOW HEATING RATE	Medium	Thermosafe Air Heating System was not able to achieve the setpoint temperature. Alarm activated 15 minutes after power on if the temperature is not within ±2.5°C of the setpoint temperature.	Temperature controller continues to operate.	Switch off the Integra 3 and verify that the Thermosafe Air Heating System cables and connector are secure and undamaged. Possible heater or controller fault. Operating the Integra 3 below its ambient temperature specification may produce this alarm.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E22	HEATED GLASS INSERT DISABLED	Low / Medium*	ITO Heated Glass Insert has come into electrical contact with the with the microscope objective and has been disabled. Alarm activates at any time.	ITO Heated Glass Insert controller power is set to 0% for the duration of electrical contact with the microscope objective.	The microscope objective must be lowered so that it does not touch the surface of the ITO Glass.
E23	HEATED INSERT CONTROLLER FAILURE	Low / Medium*	The temperature controller was not able to maintain the temperature of the Heated Stage Insert. The Heated Stage Insert has been disabled. Alarm activates at any time.	Heated Stage Insert controller power is set to 0% until the Integra 3 is re-started.	Switch off the Integra 3 and verify that the Heated Stage Insert cables and connector are secure and undamaged. Possible heater or controller fault.
E24	FAN SPEED INCORRECT	Low	Thermosafe Air Heating System fan speed is outside of the normal operating window. Alarm enabled 5 minutes after power on.	Fan continues to run in order to maintain the air flow.	Change the Thermosafe filter media pad. Possible fan or flow sensor fault.

* Low priority is set if condition appears within the first 5 seconds from power up. Medium priority is set if condition appears after the first 5 seconds from power up.

Alarm Condition Code	Message	Priority	Fault Description/ Alarm Criteria	Alarm Actions	Solution
E25	MEMORY FAULT. PLEASE SEE MANUAL	Low	Memory/ Controller Fault. During normal use controller has failed to save data. When power is switched off and then on all values will be returned to factory defaults and the screen will show 'Recalibration Required'. This includes all Calibration (eg Temperature and Height Indicator calibration) and all Settings (eg Setpoints, Serial Number)	System continues to operate until power is removed. When power is cycled the screen will show 'Recalibration Required'.	After power is switched off and then on all heating systems will need to be set up and re-calibrated (Refer to the Integra 3 Installation & Service Manual 6-54-701IM for further information or contact your distributor or RI directly). If the problem persists after re-calibration then there may be a fault with the controller. If the problem is resolved by re-calibrating then the memory may have been corrupted during saving of values eg if the Integra 3 is powered off whilst values are being saved.

Problem	Possible cause	Solution
The specimen falls off the holding pipette/ unable to get pressure to inject	Tip of the micropipette holder has not been tightened properly	Tighten the tip if necessary
	Micropipette tip could be blocked	Replace the micropipette
	There may be an air leak in the injection/ aspiration system	Check the connection of the syringe tubing at each end. If loose, cut 10mm from the end of the tubing and reconnect. Check the tubing for damage along length and replace if necessary. Replace the O-ring in the micropipette holder tip (see Figure 11-1 on page 69) if worn out. Replace the O-ring in the SAS air syringe (see Figure 11-2 on page 7068)
Poor control from SAS Syringe		Check for: - Air leaks as above - Blocked pipette
Poor control from SOS Syringe		Check for: - Air bubbles - Blocked pipette - Using correct medium and oil eg a sterile filtered paraffin oil - Oil leaks (treat as for air leaks)
Unable to aspirate/inject	Has the specimen dried up?	Heated Stage warmth can dry up an insufficiently protected specimen. A generous layer of mineral oil over the specimen will protect it from drying out.
	Are the media you are using within their shelf life?	Some media and PVP deteriorate if stored past their shelf life or if they have not been kept refrigerated during storage or transit.

SECTION 11 - CARE AND MAINTENANCE

Regular servicing by an RI authorised technician will help to ensure that your system performs at its best. We recommend a minimum of one annual inspection and service. However, this may need to be more frequent if systems are heavily used. Contact your distributor or RI's service team directly to arrange servicing. Where necessary, RI will provide all technical information required to assist in resolving problems.

For all maintenance requirements, contact your distributor or RI's service team directly.

In the event that you have a problem with RI instruments, first look at the Troubleshooting section. If you require any further help, contact your distributor or RI's service team direct. We will try to resolve the problem as quickly as possible.

No user serviceable parts.

Part numbers of replacement parts detailed in this section are as follows:

Part Number	Description
5-34-004	SAS/MPH O-ring Set
5-34-005	SAS/MPH O-ring Set with Tools
5-43-880	Thermosafe Filters, 4 Pack

Manipulators

Lever stiffness screws can be adjusted as required (see Figure 10-1 on page 53 & Figure 10-2 on page 53).

Replacing the Micropipette Holder Tip O-ring

After a period of use the rubber O-ring inside the Micropipette Holder (MPH) will become worn and will allow air leaks to affect the injection/ aspiration system. Wear is a result of the micropipette being repeatedly inserted into the MPH.

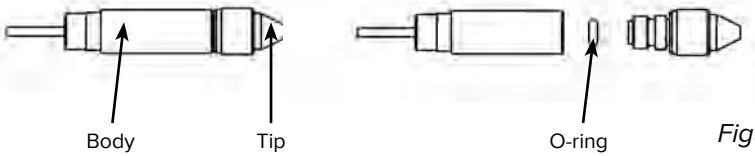


Figure 11-1

1. Unscrew the tip from the body of the MPH.
2. Remove the old O-ring. It may help to use a tool such as a small hexagon wrench to push into the centre of the O-ring to remove it.
3. Take a new O-ring from your spares kit .
4. Place the new O-ring inside the body.
5. Screw the tip back onto the body of the MPH.

Following the replacement of the O-ring and before putting into service, test the MPH in a manner representative of normal use to verify functionality.

Thermosafe Air Heating System

The Thermosafe Air Heating System contains a filter which can be easily replaced by the user. The filter is designed to prevent foreign objects and debris entering the Thermosafe Air Heating System, which could cause a degradation in performance. In all cases the Integra 3 manipulation system is expected to be used in a clean environment. Frequency of filter changes will be determined by the level of cleanliness. However, as a starting point, it is recommended that the filter should be replaced every 6 months.

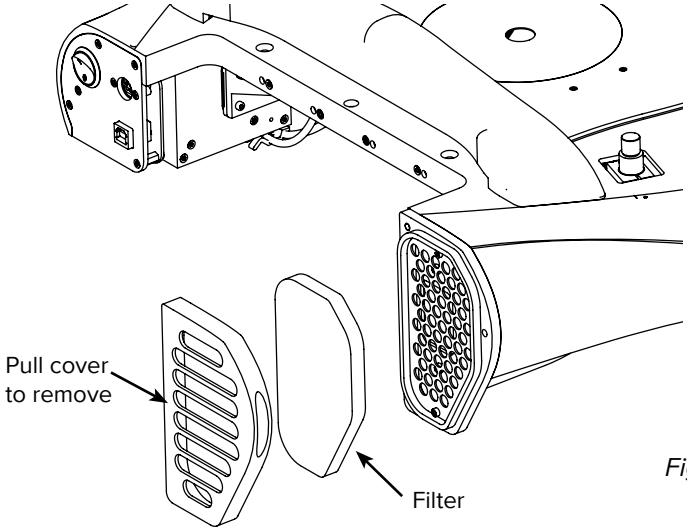


Figure 11-2

⚠ Switch the Integra 3 off before replacing the filter.

⚠ Ensure that a filter is fitted at all times and that the filter housing is correctly fitted.

Air Syringes - Inserting a New O-ring

SAS

After a lot of use the O-ring may need replacing to ensure smooth and accurate operation. Spare O-rings are supplied with the syringe, and can also be ordered from RI.

1. Unscrew the top of the syringe to reveal the black rubber O-ring. The O-ring is fitted in a groove in the lower part of the syringe.
2. Carefully remove the O-ring.
3. Place the new O-ring in the groove.
4. Reassemble.

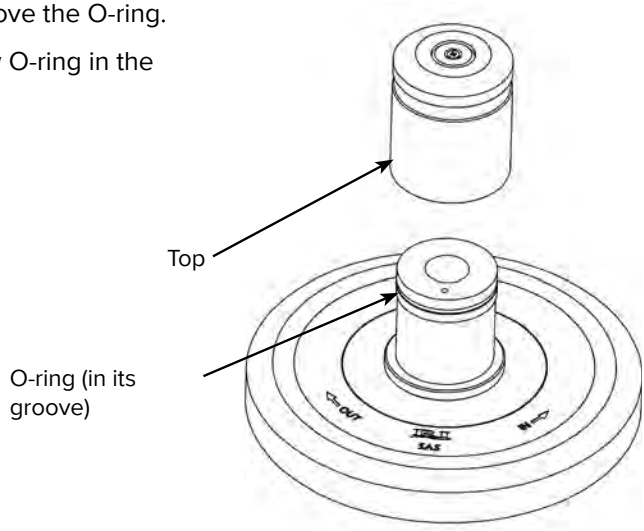


Figure 11-3

Following replacement of the O-ring and before putting into service, test the SAS in a manner representative of normal use.

SAS-SE

The SAS-SE has been designed to reduce wear on the O-ring so that replacement needs to be done less frequently. If you suspect that replacement is necessary, please contact RI as the replacement procedure is more complicated than for the SAS.

Note: Do not use oil or media in the SAS syringes

If oil or media is introduced into the system it will need to be dismantled and cleaned. This should be entrusted to an RI-authorised technician only.

Cleaning

Use a dust cover to protect the Integra 3 when not in use. This will minimise the need for cleaning. We recommend and supply a non-PVC dust cover as plasticisers commonly used in flexible PVC are known to be embryotoxic.

Always remove any spilt liquid or dirt immediately, ie keep instruments clean.

The Integra 3 can be cleaned with a soft lint-free cloth moistened with isopropyl alcohol only. This should be done with the instrument switched off at the wall switch and the instrument should be completely dry before switching on. Never use water to clean the Integra 3.

Liquid Spills

If liquid is spilt inadvertently, **immediately turn the electricity off** at the wall switch. Only then, quickly dry the instrument using paper towels or similar. If it is suspected that liquids have gone inside the instrument then contact CSI service team for advice before switching on.

Fuses

Always replace a blown fuse with a correctly rated new fuse.

Disposal of Electrical Equipment

CooperSurgical have taken the necessary steps to comply with the EC directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

If any electronic component is no longer serviceable, it must be sent back to RI to be destroyed in an environmentally safe way. Do not dispose of with ‘normal’ waste.

Dispose of the pipette and its packaging in a suitable container.

SECTION 12 - WARRANTY INFORMATION

CooperSurgical warrants that this item will be free from defects in materials and workmanship for one year from the date of installation. If CooperSurgical determines that the product fails to conform to that warranty during the one-year period, CooperSurgical will repair or replace the product, at CooperSurgical's discretion, free of charge.

To return the product to CooperSurgical, a customer must comply with CooperSurgical's Returned Goods Policy described in this manual and the warranty requires the customer to return the product to CooperSurgical in accordance with the CooperSurgical Returns Instruction. CooperSurgical will return products (that it repaired or replaced under warranty) to the same customer who returned those products, at CooperSurgical's expense F.O.B. the customer's facility. Under all other circumstances, CooperSurgical will return products to the same customer who returned those products at the customer's expense.

CooperSurgical's warranties do not cover damage caused by misuse, improper care, improper use of chemicals or cleaning methods, loss, theft, use of non-authorized parts, servicing by non-authorized personnel or negligent or intentional conduct on the part of the owner or user of the product, nor do they cover normal wear and tear or general maintenance. Any modifications or changes to a product will void that product's warranty. CooperSurgical's warranties do not apply to any single- or limited-use, disposable or consumable components or items.

CooperSurgical is not responsible for, and the owner and operator of the product shall defend, indemnify and hold harmless CooperSurgical from and against, all claims, damages, and other losses resulting from the improper servicing, maintenance, repair, use or operation of the product or the owner or operator's negligence or willful misconduct, and use of inadequate packing and packaging when returning product for repair.

The above warranties are in lieu of, and CooperSurgical hereby disclaims, all other warranties, express or implied, written or oral, with respect to CooperSurgical products, including the warranties of merchantability and fitness for a particular purpose. No terms, conditions, understandings or agreements that purport to modify the above warranties or that make any additional warranties for any CooperSurgical product shall have any legal effect unless made in writing and signed by an authorized CooperSurgical corporate officer.

CooperSurgical shall not under any circumstances be liable for lost profits,

damages from loss of use or lost data, or indirect, special, incidental or consequential damages under its warranties or otherwise for any claim related to CooperSurgical products, even if CooperSurgical has been advised, knew or should have known of the possibility of such damages. CooperSurgical's liability with respect to a product covered by a warranty or otherwise shall be limited in all circumstances to the purchase price of that product.

SECTION 13 - RETURNING PRODUCT FOR REPAIR

Please refer to the 'Troubleshooting' section in this manual before returning product. If problems continue with the device, please follow these instructions:

Returned Goods Policy

Goods will be accepted for return for the following reasons:

- If shipment was made without the customer's authorization or order
- If incorrect items were shipped
- If defective items were shipped
- If defective goods are covered by the standard warranty

To return product, please contact Customer Service for a Returned Merchandise Authorization (RMA) number. Items will not be accepted without an RMA number. Please have the following information:

- Reason for returning the goods
- Quantity, description, part number, serial number of the goods
- Date of receipt of order
- Customer's purchase order and the CooperSurgical or Origio invoice number

All used products must be cleaned and sterilized prior to shipment. A signed decontamination declaration may be required.

All products should be carefully and adequately packed, preferably in original packaging. Replacement items or additional repairs will be invoiced.

All packaging should be clearly labeled with the RMA number and statement "Urgent – Returned Items for Repair". If authorisation to return a product is granted you will be provided with a return address label.

Shipment must be sent prepaid by the customer and insured for their full value during shipping. Freight collect shipments will not be accepted, and goods will be returned to sender.

If Customer intends to return equipment ordered in error, the following restocking charges and terms will apply:

- 25 percent within 60 days from date of shipment
- Goods must be returned unused, in the original carton, and in marketable condition
- Refurbishing and replacement charges will be added to the restocking charges for damaged or missing items
- No return after 60 days
- No refund on sterile, single-use disposable products

Customer Service Contact details

Tel: +45 46 79 02 02

Fax: +45 46 79 03 02

E-mail: Sales@coopersurgical.com

fertility.coopersurgical.com

US only customers Contact details

Tel: 800-243-2974

Fax: 800-262-0105

fertility.coopersurgical.com

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