

March 30, 2020

**Mindray A-Series Anesthesia Delivery System  
Consideration for use as a Ventilator  
Addendum – Procedures for Converting Drive Gas from Oxygen to Air**

Dear Valued Customer:

This communication is an addendum to the document noted above and provided on March 23, 2020 regarding the use of Mindray A-Series Anesthesia Delivery Systems for continuous ventilation. Specifically detailed is the process for converting the systems drive gas **from oxygen to air**.

**Note: Only individuals qualified to perform maintenance/repair on anesthesia systems should carry out this conversion.**

**Systems having the drive gas modified should be prominently labeled as such and may not be used for anesthesia delivery, until the drive gas is reverted to oxygen.**

Guidance for converting the A7 system is provided under Attachment 1.  
Guidance for converting the A5 system is provided under Attachment 2.  
Guidance for converting the A3/A4 system is provided under Attachment 3.

The following are recommendations/considerations during use after a system's drive gas has been converted from oxygen to air:

1. It is strongly recommended to connect both the air and oxygen source before using the system to achieve a gas source pressure between 280-600 kPa (41-80 psi).
2. If the pressure of air is lower than 140 kPa  $\pm 10\%$  (20 psi  $\pm 10\%$ ), the system will display the alarm "Drive Gas Pressure Low" and will not ventilate.
3. If the pressure of the oxygen gas source is lower than 220 kPa  $\pm 10\%$  (32 psi  $\pm 10\%$ ) the system will display the alarm "O<sub>2</sub> Supply Failure". Under this condition, the system will continue to ventilate but the oxygen fresh gas delivered may be lower than expected.
4. If the flow sensor requires calibration after the drive gas has been converted, the tidal volume accuracy may be up to 5% over specification.

Mindray's in-house supports team remain available 24/7. If assistance is needed, please contact Technical Support at (800) 288-2121, option 2.

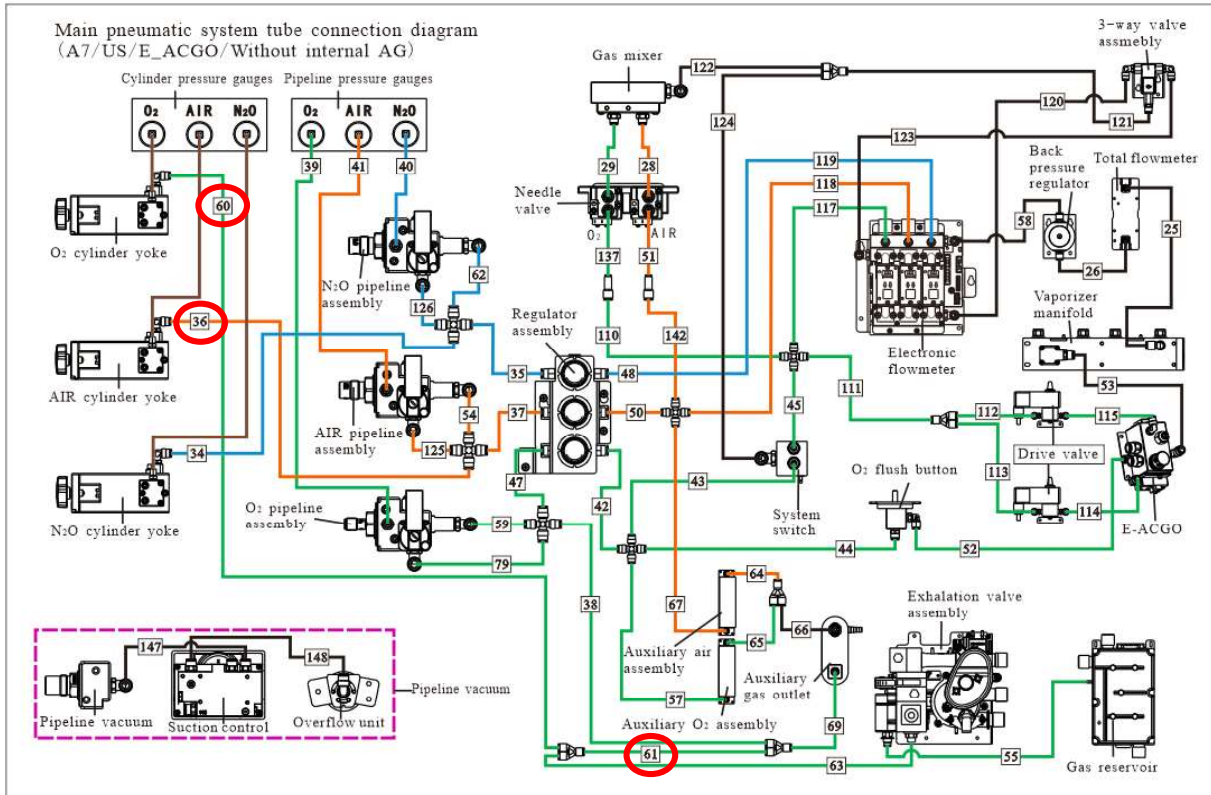
Sincerely,

Diane Arpino  
Director, Quality Operations and Regulatory Affairs  
Mindray DS USA, Inc.  
US Agent for Shenzhen Mindray Biomedical Corp., Ltd.  
[d.arpino@mindray.com](mailto:d.arpino@mindray.com)

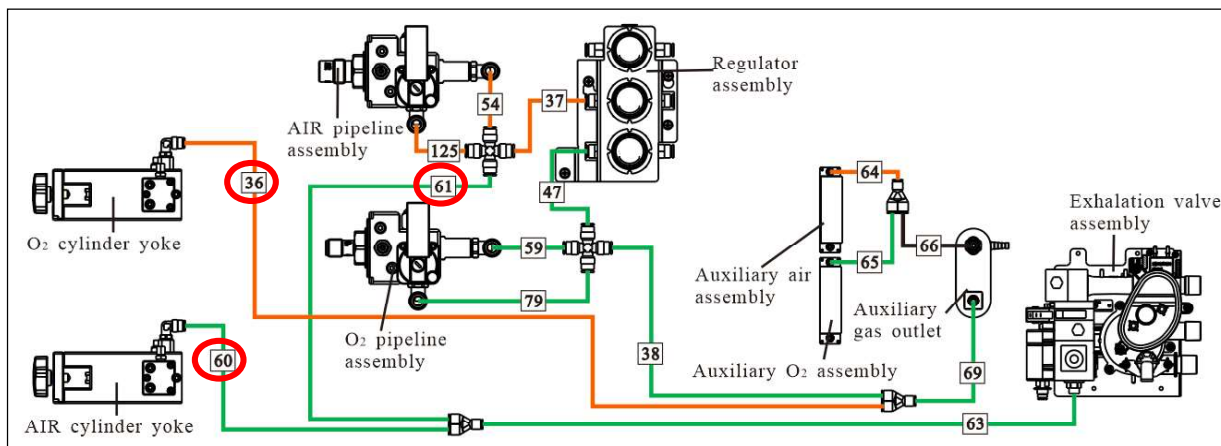
**Attachment 1**

Please follow the steps below to convert the drive gas of Mindray A7 Anesthesia delivery systems from oxygen to air, the connection diagrams before and after the change are shown below:

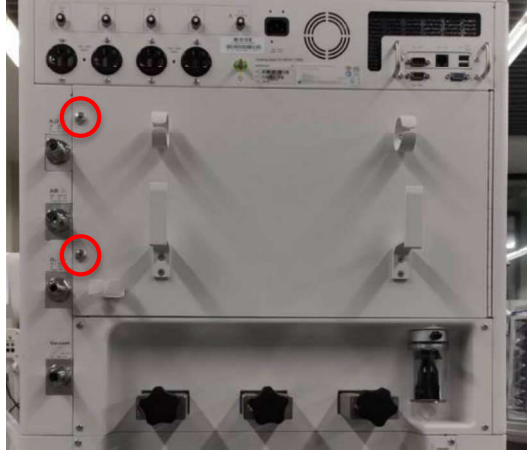
**Connection diagram before change:**



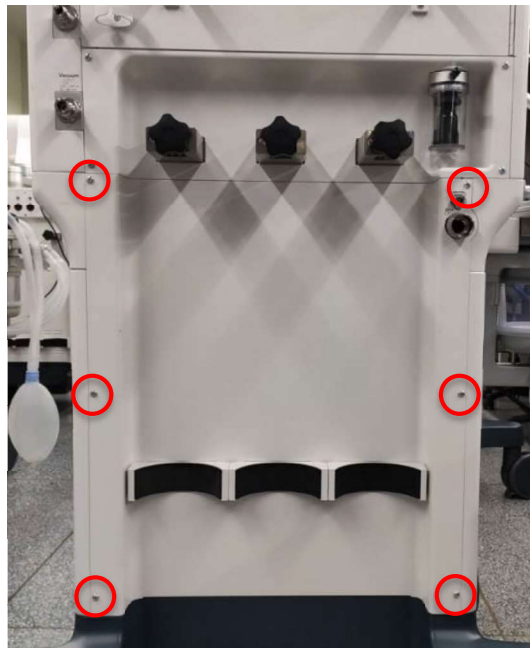
**Connection diagram after change:**



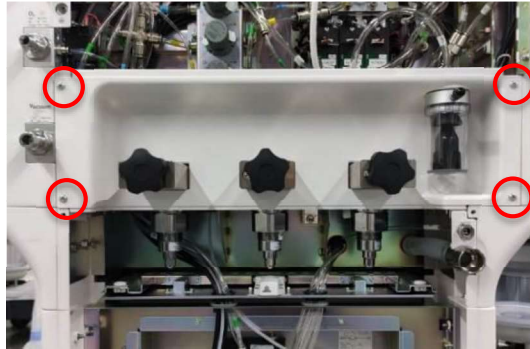
1. Open the service door: Turn the two screws on the service door counter-clockwise one half turn to open the door. (If the AGSS assembly is connected to the machine, unplug the transfer tubes from AGSS assembly).



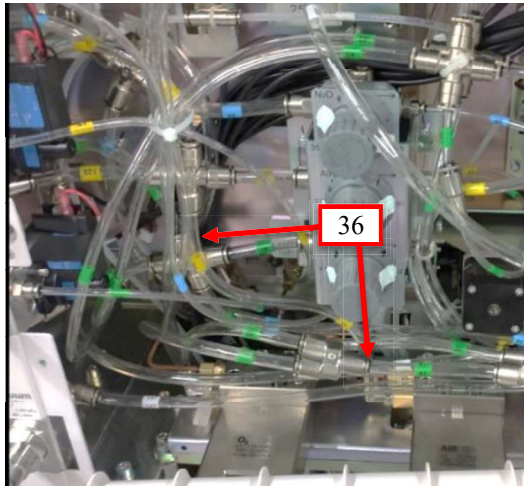
2. Remove the rear cover panel: Unscrew the six screws on the lower rear panel assembly to remove it.



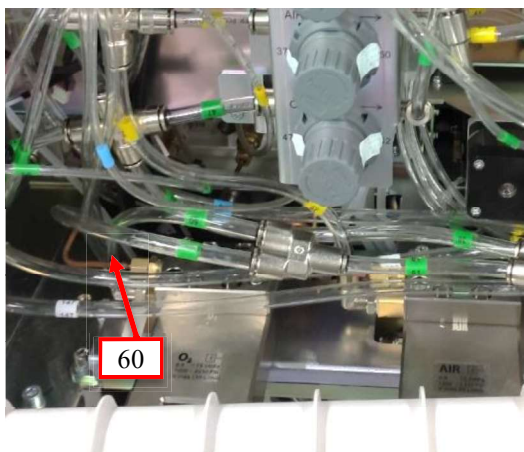
3. Remove the yoke panel: Unscrew the four screws on the upper rear panel (yoke cover) and pull it out.



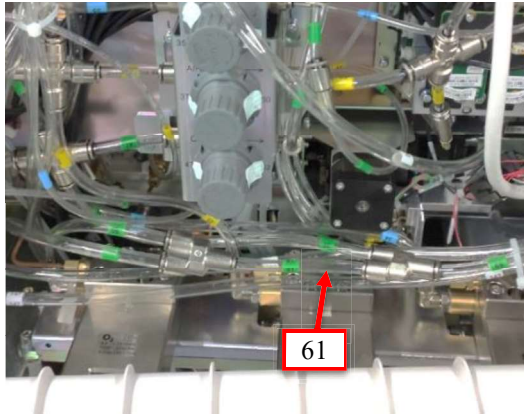
4. Remove the hose #36 (Orange) from the AIR cylinder yoke and the X-piece (connected to hoses #54, #37 and #125).



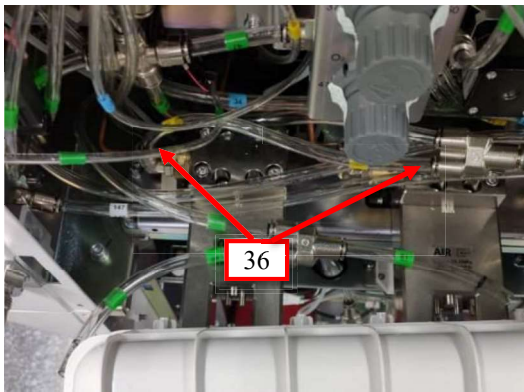
5. Disconnect the hose #60 (Green) from the oxygen cylinder yoke.



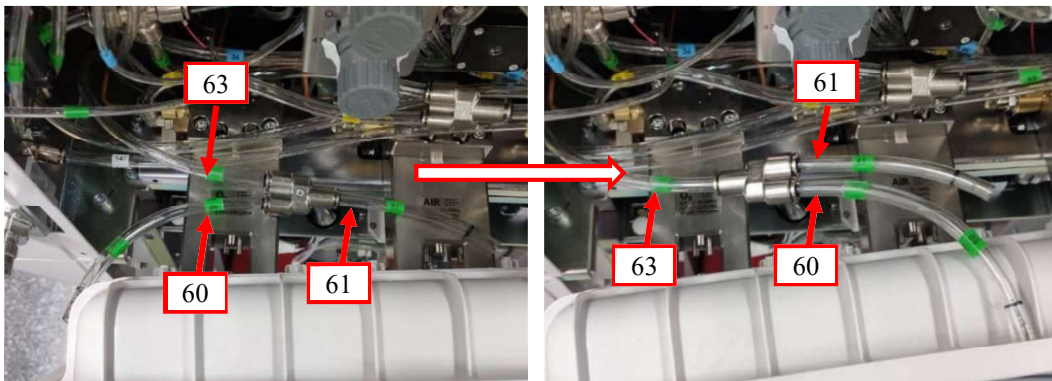
6. Disconnect hose #61 (Green) from the Y-piece (connected to hoses #69 and #38)



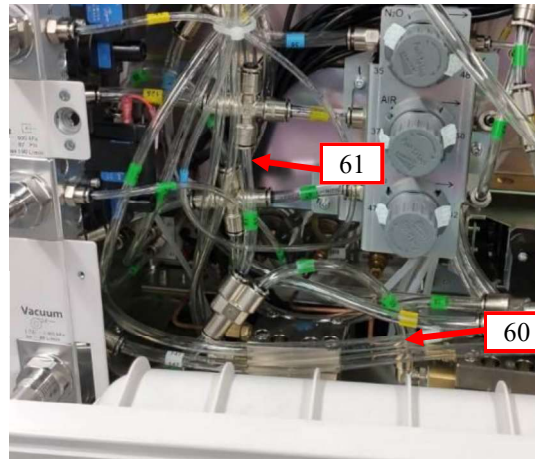
7. Connect one end of the hose #36 (Orange) to the oxygen cylinder yoke, the other end to Y-piece (connected to hoses #69 and #38).



8. Interchange the port of hose #61 (Green) and #63 (Green).



9. Connect the tube #60 (Green) to the Air cylinder yoke. Connect the opposite end of hose #61 (Green) to the X-piece (connected to hoses #54, #37 and #125).



10. Reinstall the yoke panel, the rear cover panel and service door according to the steps #3, #2, #1.
11. Perform the following Pneumatic Tests:
- Remove the O<sub>2</sub> and AIR cylinder from the anesthesia system.
  - Connect the O<sub>2</sub> and AIR line pressure hoses to the line pressure inlet on the anesthesia system.
  - Pinch the O<sub>2</sub> line pressure hose.
  - Remove the O<sub>2</sub> line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - Release the O<sub>2</sub> line pressure hose.
  - Pinch the AIR line pressure hose.
  - Remove the AIR line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - Release the AIR line pressure hose.
  - Reconnect the O<sub>2</sub> and AIR line pressure hoses and remove the pinch in the hose.
12. Perform the following Internal Gas Connections Test:
- Close and remove all gas cylinders from the anesthesia system.
  - Connect only the O<sub>2</sub> line pressure hose to the anesthesia system from the wall supply. Leave all other line pressure hoses disconnected.
  - Turn the unit on and set the A7 in BFCS mode, Rotate the O<sub>2</sub> needle valve knob to ensure a continuous flow increase throughout its full range. Set the O<sub>2</sub> flow to 2L/min.
  - Fully rotate the AIR needle valve knob and verify that there is no increase of total flow. Close the AIR valve.
  - Disconnect the O<sub>2</sub> line pressure hose from the anesthesia system, and connect the AIR line pressure hose from the wall supply.
  - Rotate the AIR needle valve knob to ensure a continuous flow increase throughout its full range.
  - Set the AIR flow to 2L/min.
  - Fully rotate the O<sub>2</sub> needle valve knob and verify that there is no increase of total flow.

- 
- 
- i) Close the AIR and O2 valves.
  - j) Disable Backup Flow Control.
13. Perform the following VCV Adult Ventilation Mode Test:
- a) Set the Fresh Gas Control to Direct Flow Mode.
  - b) Set the O2 flow to 2L/min and set the N2O and AIR flow rates to minimum flow.
  - c) Set the mechanical Auto/Manual switch to AUTO.
  - d) Connect a Vent Tester to the breathing system. Unidirectional Vent Testers need to be connected to the expiratory limb.
  - e) Set the ventilator controls to the following:
    - i. Ventilation Mode: VCV
    - ii. Vt: 600
    - iii. Rate: 8
    - iv. I:E: 1:2
    - v. Tpause: 10
    - vi. PEEP: Off
    - vii. Plimit: 50
  - f) Verify that the pressure waveform, Tidal Volume, Mean or Plateau Pressure, Resp. rate and minute volume values appear on the screen.
  - g) Verify the Tidal Volume display on the Vent Tester is within 12% ( $\pm 72$  mL) of the set value within approximately 1 minute from the start of ventilation.
  - h) Verify the Tidal Volume display is within 14% ( $\pm 84$  mL) of the set value within approximately 1 minute from the start of ventilation.
14. Prominently label the unit that the drive gas has been modified and the system may be used.

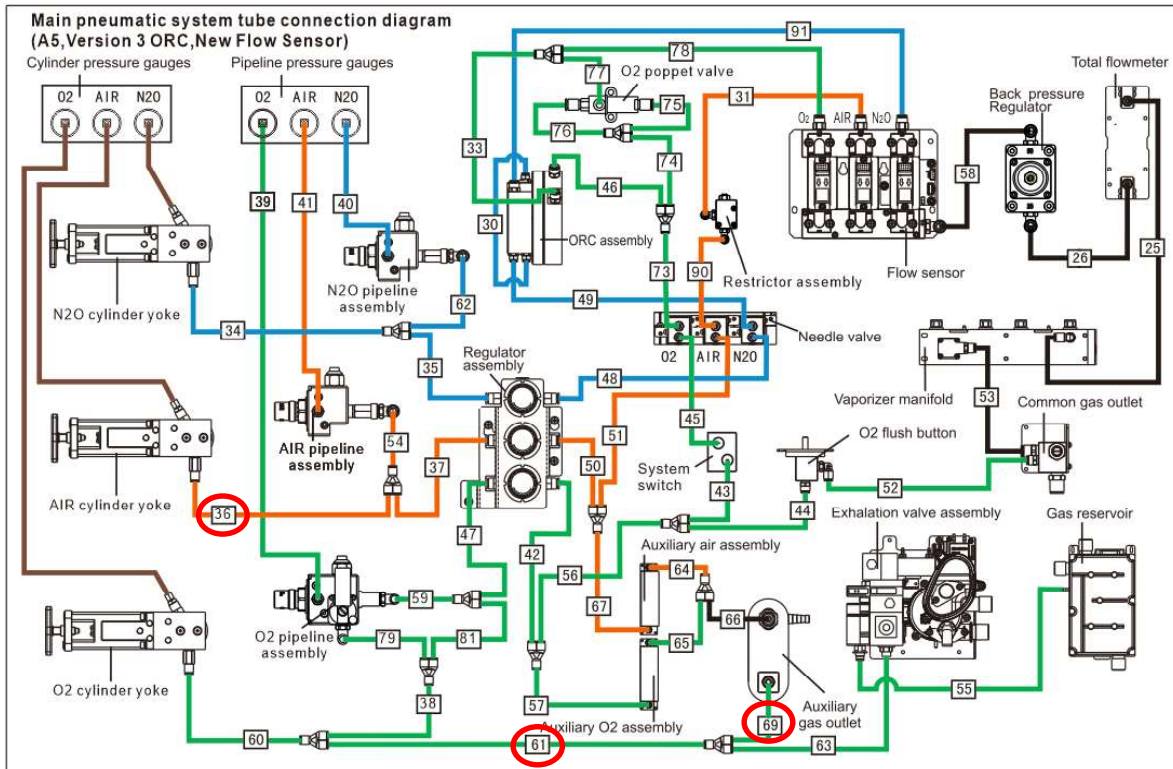
Please follow the steps below to convert the drive gas of Mindray A7 Anesthesia delivery systems from air to oxygen.

1. The systems should be converted back to using oxygen as the drive gas by performing the above steps in reverse.
2. Perform the Pneumatic Leak Tests per chapter 3.9 of the service manual
3. Perform the Internal Gas Connections Test per chapter 3.10.2 of the service manual
4. Perform a flow calibration per chapter 4.3.3 (Flow Calibration (Service)) of the service manual
5. Perform the chapter 3.11 (Performance Verification) of the service manual
6. The label that was added to the unit that the drive gas was been modified should be removed and the system may be used for anesthesia delivery.

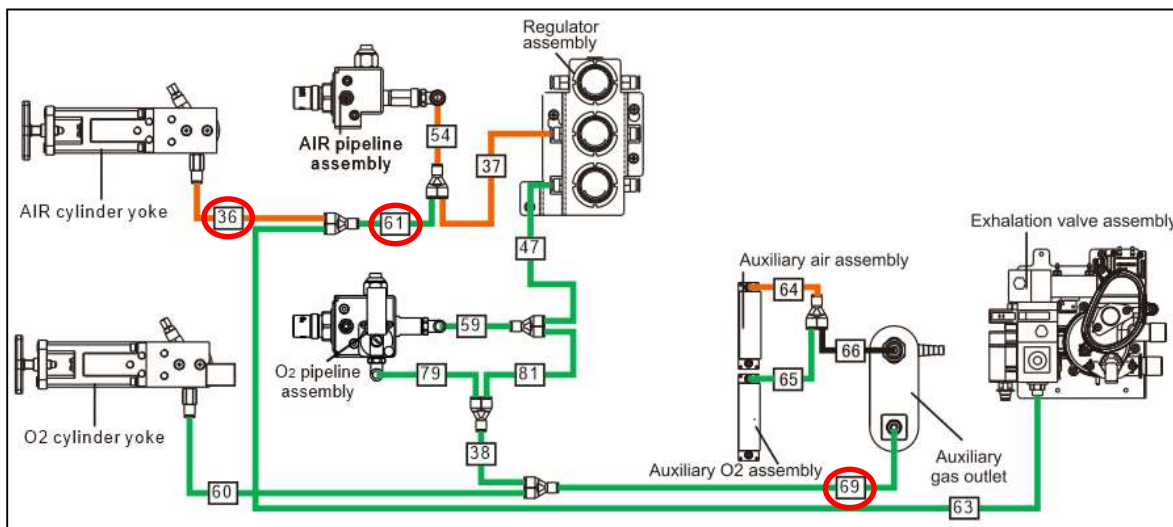
**Attachment 2**

Please follow the steps below to convert the drive gas of Mindray A5 Anesthesia delivery systems from oxygen to air. The connection diagrams before and after change are shown below:

**Connection diagram before change:**

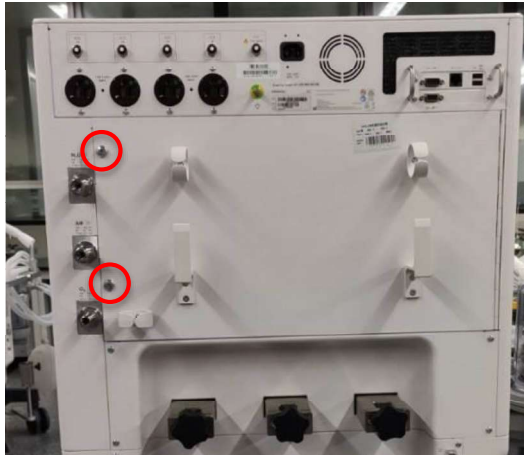


**Connection diagram after change:**

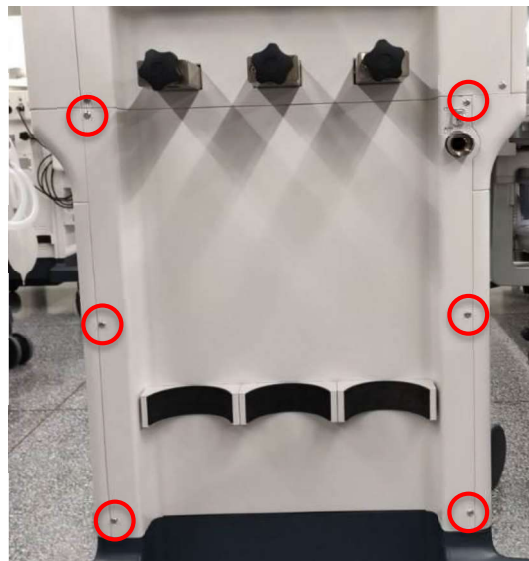




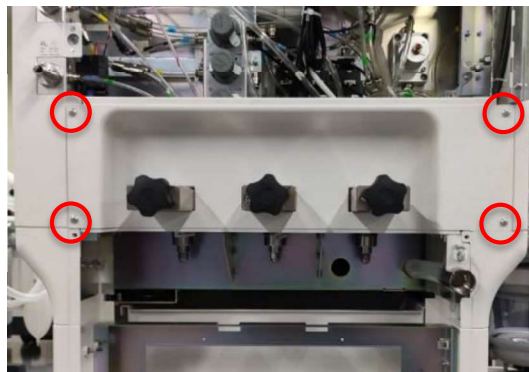
1. Open the service door: Turn the two screws on the service door counter-clockwise one half turn to open the door (If the AGSS assembly is connected to the machine, unplug the transfer tubes from AGSS assembly).



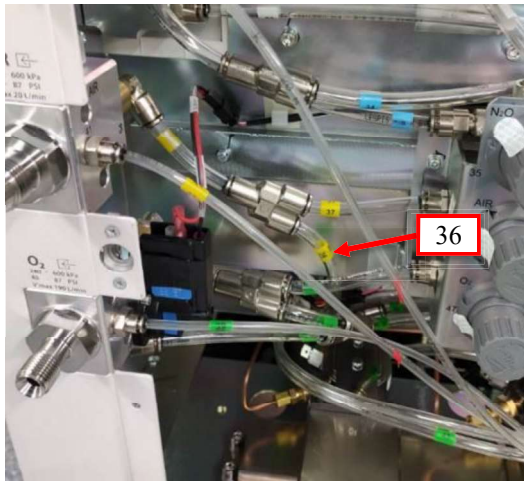
2. Remove the rear cover panel: Unscrew the six screws on the lower rear panel assembly to remove it.



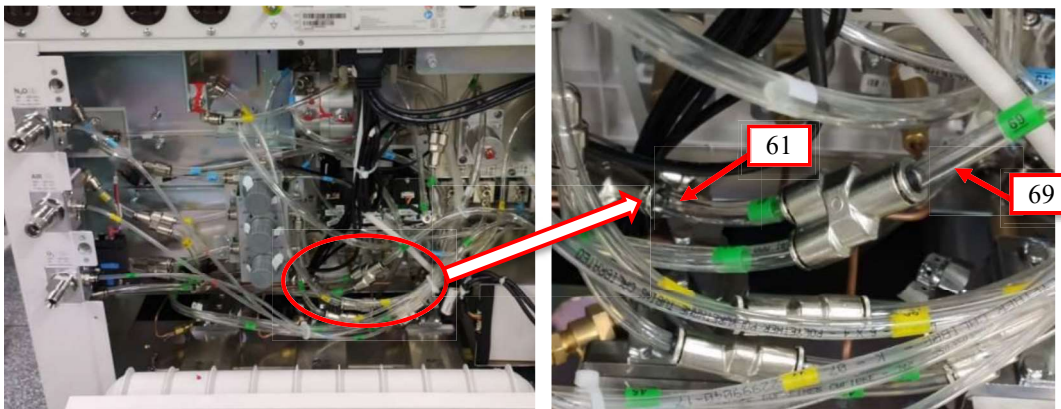
3. Remove the yoke panel: Unscrew the four screws on the upper rear panel (yoke cover) and pull it out.



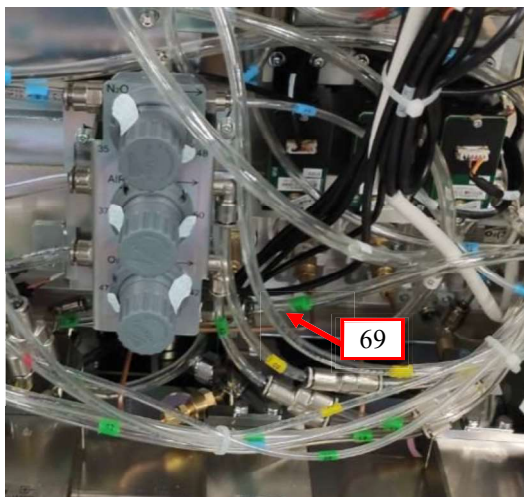
4. Disconnect hose #36 (Orange) from the Y-piece (connected to hoses #54 and #37).



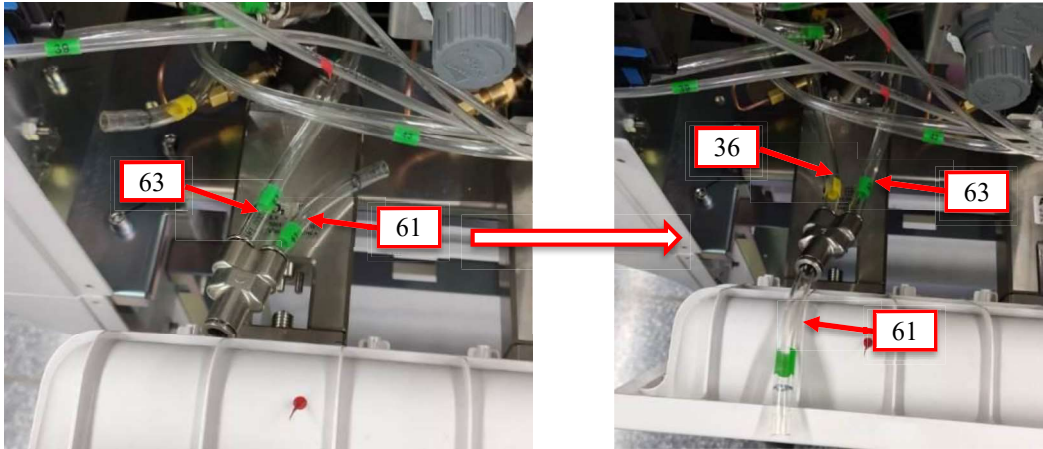
5. Disconnect the hose #61 (Green) from the Y-piece (connected to hoses #60 and #38).  
Disconnect hose #69 (Green) from the Y-piece (connected to hoses #61 and #63).



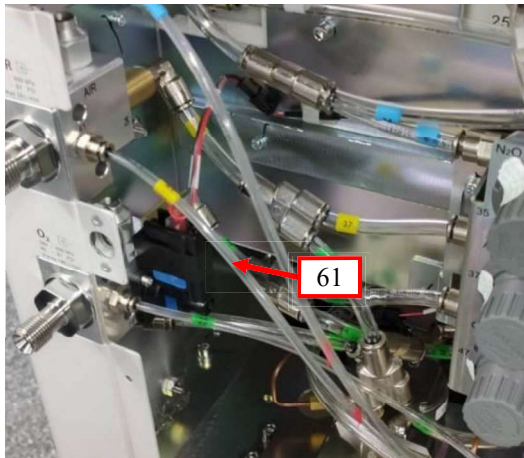
6. Connect hose #69 (Green) to the Y-piece (connected to hoses #60 and #38).



7. Remove the hose #61 (Green) and connect it to the outlet of Y-piece (the side with only one outlet), connect the hose #36 (Orange) and to another outlet of Y-piece (the side with two outlets).



8. Connect the opposite end of hose #61 (Green) to the Y-piece (connected to hoses #54 and #37).



9. Reinstall the yoke panel, rear cover panel service door and AGSS (if applicable) according to the steps #3, #2, and #1.
10. Perform the following Pneumatic Leak Tests:
  - a) Remove the O<sub>2</sub> and AIR cylinder from the anesthesia system.
  - b) Connect the O<sub>2</sub> and AIR line pressure hoses to the line pressure inlet on the anesthesia system.
  - c) Pinch the O<sub>2</sub> line pressure hose.
  - d) Remove the O<sub>2</sub> line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - e) Release the O<sub>2</sub> line pressure hose.
  - f) Pinch the AIR line pressure hose.
  - g) Remove the AIR line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - h) Release the AIR line pressure hose.
  - i) Reconnect the O<sub>2</sub> and AIR line pressure hoses and remove the pinch in the hose.

- 
11. Perform the following Internal Gas Connections Test:
    - a) Close and remove all gas cylinders from the A5.
    - b) Connect only the AIR line pressure hose to the A5 from the wall supply. Leave all other line pressure hoses disconnected.
    - c) With the A5 powered ON, rotate the AIR flow control knob to ensure a continuous flow increase throughout its full range.
    - d) Fully rotate the N2O flow control knob and verify that there is no flow.
    - e) Fully rotate the O2 flow control knob and verify that there is no flow.
    - f) Disconnect the AIR line pressure hose from the A5 and connect the O2 line pressure hose from the wall supply, rotate the O2 flow control knob to ensure a continuous flow increase throughout its full range (0 to 15L/min).
    - g) Fully rotate the N2O flow control knob and verify that there is no flow.
    - h) Fully rotate the AIR flow control knob and verify that there is no flow.
    - i) Connect the N2O line pressure hose from the wall supply. With the O2 flow control knob fully opened, rotate the N2O flow control knob to ensure a continuous flow increase throughout its full range. Skip this step if N2O supply is not available
    - j) Fully rotate the AIR flow control knob and verify that there is no flow. Skip this step if N2O supply is not available
    - k) Close all 3 flow control knobs and reconnect the AIR line pressure hose.
  
  12. Perform the following VCV Adult Ventilation Mode Test:
    - a) Set the O2 flow to 2 L/min and set the N2O and AIR flow rates to minimum flow.
    - b) Set the mechanical Auto/Manual switch to AUTO.
    - c) Connect a Vent Tester to the breathing system. Unidirectional Vent Testers need to be connected to the expiratory limb.
    - d) Set the ventilator controls to the following:
      - i. Ventilation Mode: VCV
      - ii. Vt: 600
      - iii. Rate: 8
      - iv. I:E: 1:2
      - v. Tpause: 10
      - vi. PEEP: Off
      - vii. Plimit: 50
    - e) Verify that the pressure waveform, Tidal Volume, Mean or Plateau Pressure, Resp. rate and minute volume values appear on the screen.
    - f) Verify the Tidal Volume display on the Vent Tester is within 12% ( $\pm 72$  mL) of the set value within approximately 1 minute from the start of ventilation.
    - g) Verify the Tidal Volume display is within 14% ( $\pm 84$  mL) of the set value within approximately 1 minute from the start of ventilation.
  
  13. Prominently label the unit that the drive gas has been modified and the system may be used.

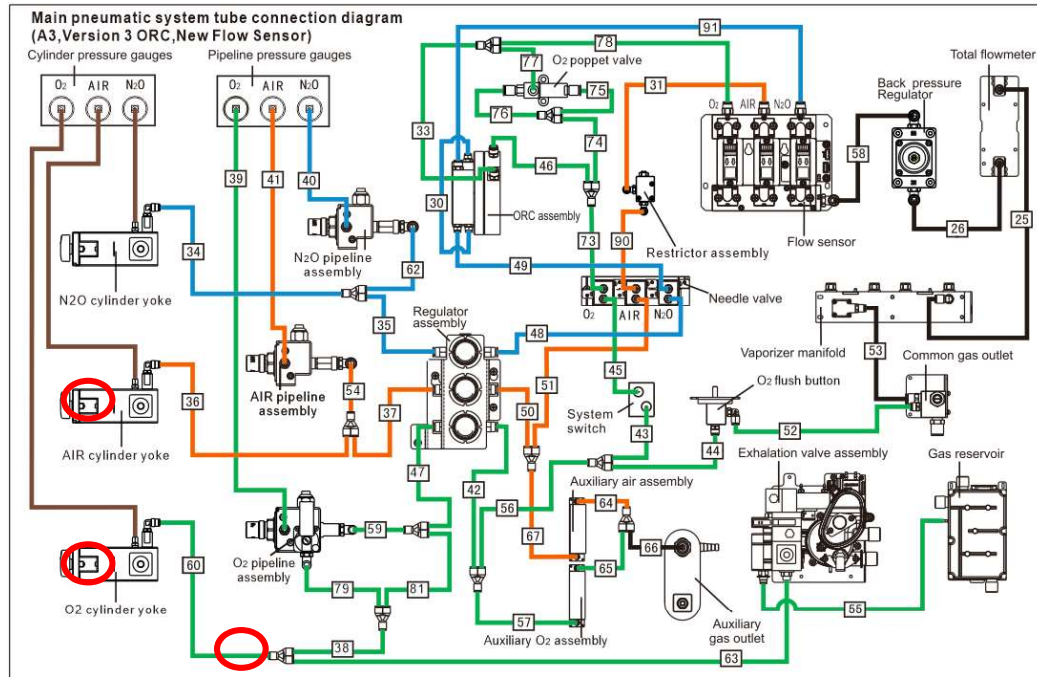
Please follow the steps below to convert the drive gas of Mindray A5 Anesthesia delivery systems from air to oxygen.

1. The systems should be converted back to using oxygen as the drive gas by performing the above steps in reverse.
2. Perform the Pneumatic Leak Tests per chapter 3.9 of the service manual
3. Perform the Internal Gas Connections Test per chapter 3.10.2 of the service manual
4. Perform a flow calibration per chapter 4.3.3 (Flow Calibration (Service)
5. of the service manual
6. Perform the chapter 3.11 (Performance Verification) of the service manual
7. The label that was added to the unit that the drive gas was been modified should be removed and the system may be used for anesthesia delivery.

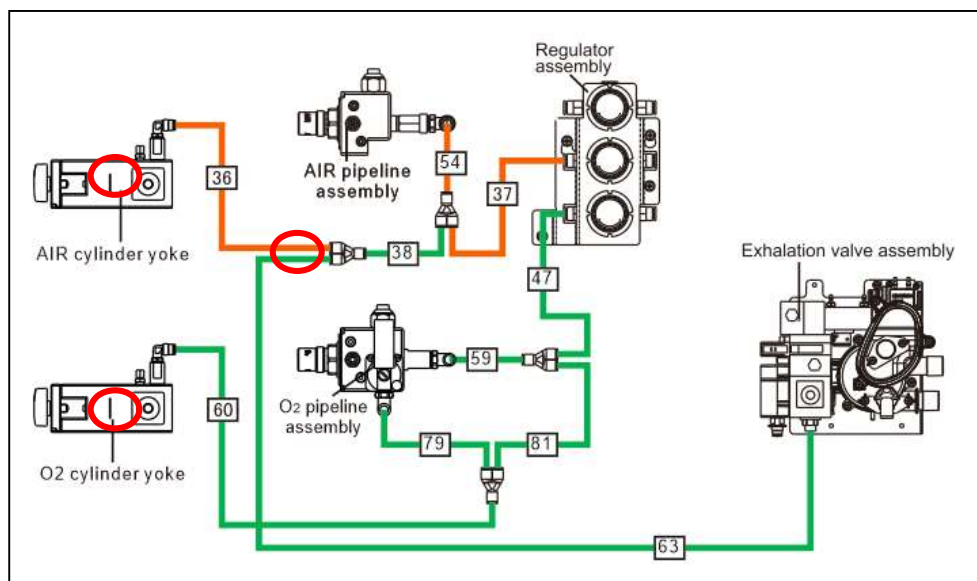
**Attachment 3**

Please follow the steps below to convert the drive gas of Mindray A3/A4 Anesthesia delivery systems from oxygen to air (Please note the A4 doesn't have N2O gas yoke). The connection diagrams before and after change are shown below:

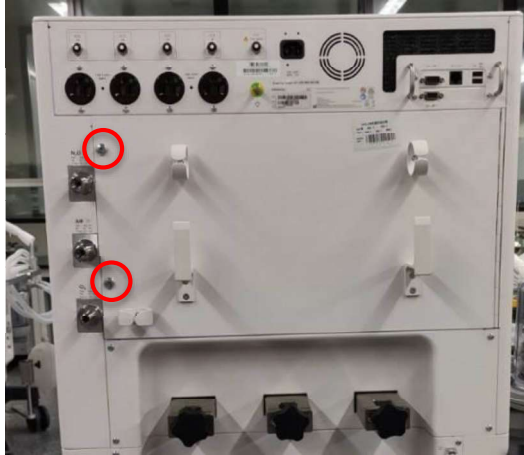
**Connection diagram before change:**



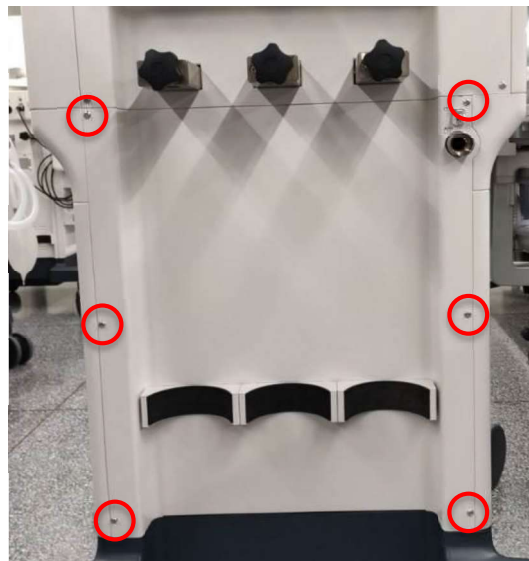
**Connection diagram after change:**



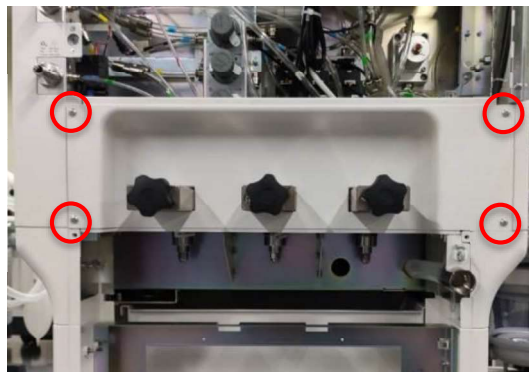
1. Open the service door: Turn the two screws on the service door counter-clockwise one half turn to open the door (If the AGSS assembly is connected to the machine, unplug the transfer tubes from AGSS assembly)



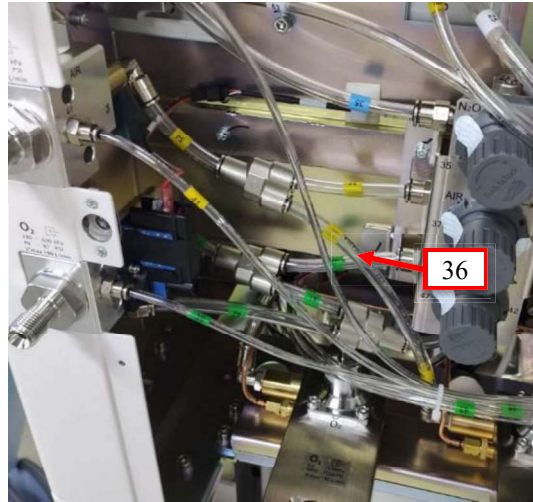
2. Remove the rear cover panel: Unscrew the six screws on the lower rear panel assembly to remove it.



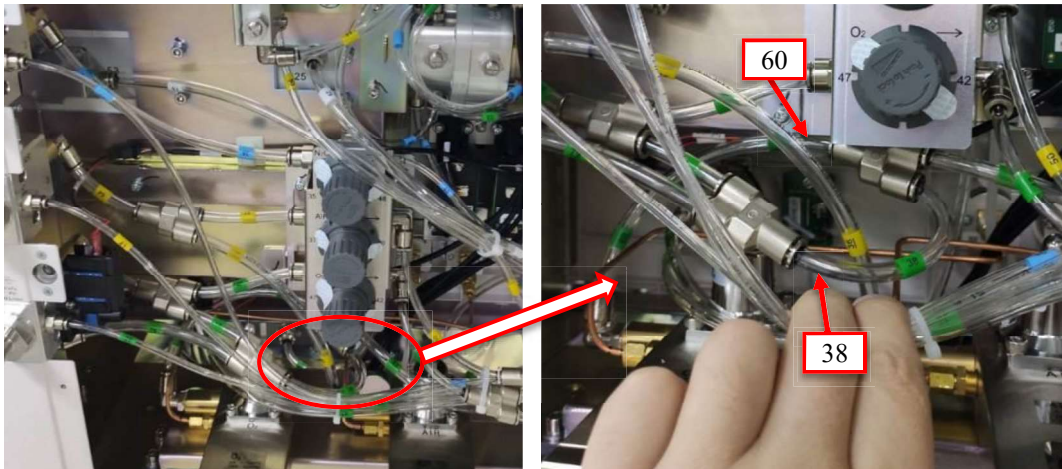
3. Remove the yoke panel: Unscrew the four screws on the upper rear panel (yoke cover) and pull it out.



4. Disconnect hose #36 (Orange) from the Y-piece (connected to hoses #54 and #37).

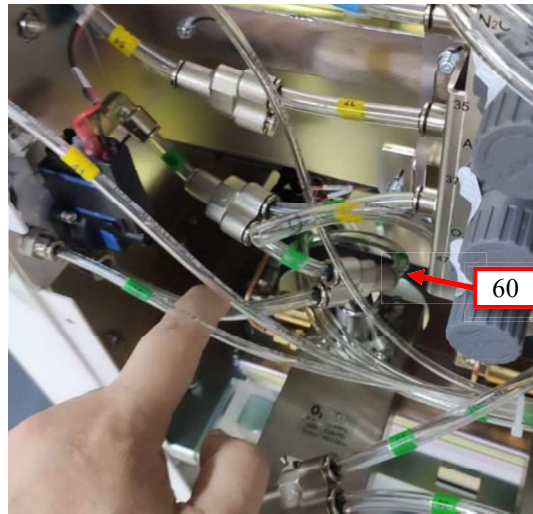


5. Disconnect hose #60 (Green) from the Y-piece (connected to hoses #38 and #63).  
Disconnect hose #38 (Green) the Y-piece (connected to hoses #79 and #81).

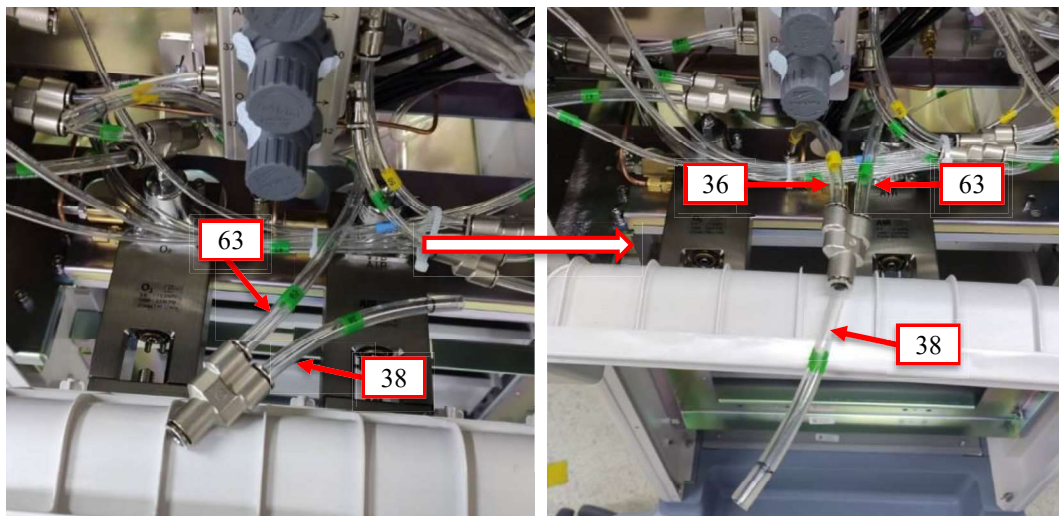




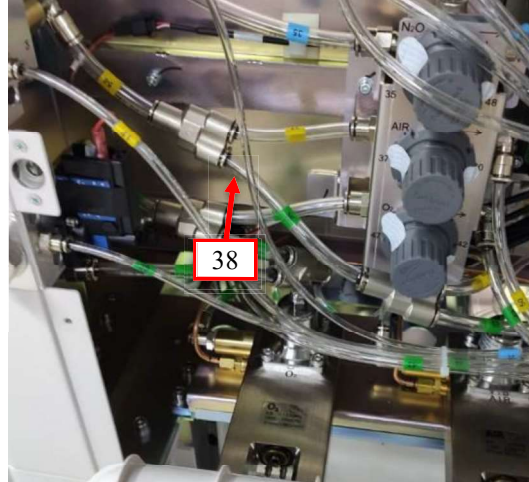
6. Connect hose #60 (Green) to the Y-piece (connected to hoses #79 and #81).



7. Remove the hose #38 (Green) and connect it to the outlet of Y-piece (the side with only one outlet), connect the hose #36 (Orange) and to another outlet of Y-piece (the side with two outlets).



8. Connect the opposite end of hose #38 (Green) to the Y-piece (connected to hoses #54 and #37).



9. Connect the Air/O<sub>2</sub> pipeline supply, check if abnormal sound due to leakage occurs.
10. Reinstall the yoke panel, the rear cover panel, the service door and AGSS if applicable) according to the steps #3, #2, # 1 in Attachment 1.
11. Perform the following Pneumatic Leak Tests:
- Remove the O<sub>2</sub> and AIR cylinder from the anesthesia system.
  - Connect the O<sub>2</sub> and AIR line pressure hoses to the line pressure inlet on the anesthesia system.
  - Pinch the O<sub>2</sub> line pressure hose.
  - Remove the O<sub>2</sub> line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - Release the O<sub>2</sub> line pressure hose.
  - Pinch the AIR line pressure hose.
  - Remove the AIR line pressure hose from the line source while keeping the hose pinched. The pressure measured on the line pressure gauge on the front of the unit should not fall more than 10 psi per 100 seconds (2 psi per 20 sec).
  - Release the AIR line pressure hose.
  - Reconnect the O<sub>2</sub> and AIR line pressure hoses and remove the pinch in the hose.
12. Perform the following Internal Gas Connections Test:
- Close and remove all gas cylinders from the A3/A4.
  - Connect only the AIR line pressure hose to the A3/A4 from the wall supply. Leave all other line pressure hoses disconnected.
  - With the A3/A4 powered ON, rotate the AIR flow control knob to ensure a continuous flow increase throughout its full range.
  - Fully rotate the N<sub>2</sub>O flow control knob and verify that there is no flow.
  - Fully rotate the O<sub>2</sub> flow control knob and verify that there is no flow.
  - Disconnect the AIR line pressure hose from the A3/A4 and connect the O<sub>2</sub> line pressure hose from the wall supply, rotate the O<sub>2</sub> flow control knob to ensure a continuous flow increase throughout its full range (0 to 15 L/min).
  - Fully rotate the N<sub>2</sub>O flow control knob and verify that there is no flow.
  - Fully rotate the AIR flow control knob and verify that there is no flow.

- i. Connect the N2O line pressure hose from the wall supply. With the O2 flow control knob fully opened, rotate the N2O flow control knob to ensure a continuous flow increase throughout its full range. Skip this step if N2O supply is not available
  - j. Fully rotate the AIR flow control knob and verify that there is no flow. Skip this step if N2O supply is not available
  - k. Close all 3 flow control knobs and reconnect the AIR line pressure hose.
13. Perform the following VCV Adult Ventilation Mode Test:
- a. Set the O2 flow to 2 L/min and set the N2O and AIR flow rates to minimum flow.
  - b. Set the mechanical Auto/Manual switch to AUTO.
  - c. Connect a Vent Tester to the breathing system. Unidirectional Vent Testers need to be connected to the expiratory limb.
  - d. Set the ventilator controls to the following:
    - i. Ventilation Mode: VCV
    - ii. Vt: 600
    - iii. Rate: 8
    - iv. I:E: 1:2
    - v. Tpause: 10
    - vi. PEEP: Off
    - vii. Plimit: 50
  - e. Verify that the pressure waveform, Tidal Volume, Mean or Plateau Pressure, Resp. rate and minute volume values appear on the screen.
  - f. Verify the Tidal Volume display on the Vent Tester is within 12% ( $\pm 72$  mL) of the set value within approximately 1 minute from the start of ventilation.
  - g. Verify the Tidal Volume display is within 14% ( $\pm 84$  mL) of the set value within approximately 1 minute from the start of ventilation.
14. Prominently label the unit that the drive gas has been modified and the system may be used.

Please follow the steps below to convert the drive gas of Mindray A4/A3 Anesthesia delivery systems from air to oxygen.

1. The systems should be converted back to using oxygen as the drive gas by performing the above steps in reverse.
2. Perform the Pneumatic Leak Tests per chapter 3.9 of the service manual
3. Perform the Internal Gas Connections Test per chapter 3.10.2 of the service manual
4. Perform a flow calibration per chapter 4.3.3 (Flow Calibration (Service)) of the service manual
5. Perform the chapter 3.11 (Performance Verification) of the service manual
6. The label that was added to the unit that the drive gas was been modified should be removed and the system may be used for anesthesia delivery.