WATO EX-35 Anesthesia Machine

Operator's Manual

CE 0123

For this Operator's Manual, the issue date is March, 2015.

6 Preoperative Test

6.1 Preoperative Test Schedules

6.1.1 Test Intervals

Perform the preoperative tests listed below at these events:

1. Before each patient.
2. When required after a maintenance or service procedure.

The following table indicates when a test must be done.

Test Item	Test Intervals
Pipeline tests	Every day before the first patient
Cylinder tests	
Backup Oxygen supply tests	
Flow control system tests	
Vaporizer Back Pressure Test	
Inspect the system	Before each patient
Alarm tests	
Power failure alarm test	
Breathing system tests	
Preoperative preparations	
Inspect the AGSS	

NOTE

- **Read and understand the operation and maintenance of each component before using the anesthesia machine.**
- **Do not use the anesthesia machine if a test failure occurs. Contact us immediately.**
- **A checklist of the anesthetic system should be provided including anesthetic gas delivery system, monitoring device, alarm system and protective device which are intended to be used for the anesthetic system, whether they are used alone or assembled together.**

6.2 Inspect the System

NOTE

- **Make sure that the breathing system is correctly connected and not damaged.**
- **The top shelf weight limit is 30 kg.**

Make sure that:

1. The anesthesia machine is undamaged.
2. All components are correctly attached.
3. The breathing system is correctly connected, and the breathing tubes are undamaged.
4. The vaporizers are locked in position and contain sufficient agent.
5. The gas supplies are connected and the pressures are correct.
6. Cylinder valves are closed on models with cylinder supplies (Verify that the cylinder wrench (095-000031-00) is attached.).
7. The necessary emergency equipment is available and in good condition.
8. Equipment for airway maintenance and tracheal intubation is available and in good condition.
9. Inspect the color of the absorbent in the canister. Replace the absorbent immediately if obvious color change is detected.
10. Applicable anesthetic and emergency drugs are available.
11. The casters are not damaged or loose and the brake(s) is set and prevents movement.
12. The breathing system is locked by checking the locking button for the system.
13. The AC mains indicator comes on when the power cord is connected to the AC power source. If the indicator is not on, the system does not have electrical power.
14. The anesthesia machine is switched on or off normally.

6.3 Power Failure Alarm Test

1. Set the system switch to the ⊙ position.
2. Disconnect the AC mains.
3. Make sure that the AC mains indicator is extinguished and the system prompts [**Battery in Use**].
4. Reconnect the AC mains.
5. Make sure that the AC mains indicator is illuminated and the prompt message [**Battery in Use**] disappears.
6. Set the system switch to the Ō position.

6.4 Pipeline Tests

NOTE

- **Do not leave gas cylinder valves open if the pipeline supply is in use. Cylinder supplies could be depleted, leaving an insufficient reserve supply in case of pipeline failure.**

6.4.1 O2 Pipeline Test

1. Close all cylinder valves and connect an O_2 supply if the anesthesia machine is equipped with cylinders.
2. Set the system switch to the ⊙ position.
3. Set the flow controls to mid range.
4. Make sure that all pipeline pressure gauges show 280 to 600 kPa.
5. Disconnect the O_2 supply.
6. As O_2 pressure decreases, alarms for [**O2 Supply Failure**] and [**Drive Gas Pressure Low**] should occur.
7. Make sure that the O_2 gauge goes to zero.

6.4.2 N2O Pipeline Test

Connect an O_2 supply before doing the N_2O pipeline test. For details, refer to ***6.4.1O2 Pipeline Test***

NOTE

- **When doing the N_2O pipeline test, connect O_2 supply first to enable N_2O flow control.**
- **Different from O_2 pipeline supply, when N_2O supply is disconnected, no alarms related to N_2O pressure occur as N_2O pressure decreases.**

6.4.3 Air Pipeline Test

For details about Air pipeline test, refer to ***6.4.1O2 Pipeline Test***

NOTE

- **Different from O2 pipeline supply, when Air supply is disconnected, no alarms related to Air pressure occur as Air pressure decreases.**

6.5 Cylinder Tests

You do not need to perform cylinder tests if the anesthesia machine is not equipped with cylinders.

6.5.1 Check the Cylinder in Full Status

Check the cylinders of the anesthesia machine one by one as follows:

1. Set the system switch to the  position and connect the cylinders.
2. Open the valve of the cylinder to be checked. Make sure that the valves of other cylinders are closed.
3. Make sure that the cylinder being checked has sufficient pressure. If not, close the applicable cylinder valve and install a full cylinder.
4. Close the valve of the checked cylinder.

6.5.2 O2 Cylinder High Pressure Leak Test

1. Set the system switch to the position and stop O_2 pipeline supply.
2. Turn off the O_2 flowmeter.
3. Open the O_2 cylinder valve.
4. Record the current cylinder pressure.
5. Close the O_2 cylinder valve.
6. Record the cylinder pressure after one minute.
   - If the cylinder pressure decreases more than 5000 kPa (725 psi), there is a leak. Install a new cylinder gasket as described in ***10.5***. Repeat steps 1 through 6. If the leak continues, do not use the cylinder supply system.

6.5.3 N2O Cylinder High Pressure Leak Test

Refer to ***6.5.2*** to do the N2O cylinder high pressure leak test. For N_2O cylinder, a pressure decrease of more than 700 kPa (100 psi) in one minute represents a leak.

6.5.4 AIR Cylinder High Pressure Leak Test

Refer to ***6.5.2*** to do the AIR cylinder high pressure leak test.

6.6 Backup Oxygen Supply Tests

It is no need to operate this test if the system does not configure with backup oxygen supply.

1. Connect the backup oxygen cylinder to the backup oxygen supply connector.
2. Set the system switch to .
3. Turn on the valve of the oxygen cylinder.
4. Adjust the flow control knob to control the flow at the middle level within the measure range.
5. Make sure that the value of the oxygen pipeline pressure gauge is within the range of 280 kPa to 600 kPa.
6. Turn off the valve of the oxygen cylinder.
7. As the pressure of Oxygen reduces, the [**O2 Supply Failure**] alarm and [**Drive Gas Pressure Low**] alarm will be triggered.
8. Make sure that the value of the oxygen pipeline pressure gauge is bake to zero.

6.7 Flow Control System Tests

6.7.1 Without O2 Concentration Monitoring

⚠WARNING

- **Sufficient O_2 in the fresh gas may not prevent hypoxic mixtures in the breathing system.**
- **If N_2O is available and flows through the system during this test, use a safe and approved procedure to collect and remove it.**
- **Incorrect gas mixtures can cause patient injury. If the O_2-N_2O Link system does not supply O_2 and N_2O in the correct proportions, do not use the system.**

NOTE

- **Slowly open the cylinder valves to avoid damage. Do not adopt flow controls forcibly.**
- **After doing the cylinder tests, close all cylinder valves if cylinder supplies are not used.**
- **Turn the flow controls slowly. Do not turn further when the flow indicated on the flowmeter is outside the range to avoid damaging the control valve. When the flow control is turned to the minimum, the reading indicated on the flowmeter should be zero.**

To do the flow control system tests:

1. Connect the pipeline supplies or slowly open the cylinder valves.
2. Turn all flow controls fully clockwise (minimum flow).
3. Set the system switch to the ⊙ position.
4. Do not use the system if low battery or other ventilator failure alarms occur.

5. Test the O_2-N_2O Link system with flow increasing:

   Turn the N_2O and O_2 flow controls fully clockwise (minimum flow). Then turn the N_2O flow control counterclockwise and set the N_2O flow control to the rates shown in the table. The O_2 flow must meet the requirement listed in the following table.

Step	**N2O flow (L/min)**	**O2 flow (L/min)**
1	0.6	≥0.2
2	1.5	≥0.4
3	3.0	≥0.8
4	7.5	≥2.0

6. Test the O_2-N_2O Link system with flow decreasing:

   Turn the N_2O and O_2 flow controls and set the N_2O flow to 9.0 L/min and the O_2 flow to above 3 L/min respectively. Then slowly turn the O_2 flow control clockwise and set the N_2O flow control to the rates shown in the table. The O_2 flow must meet the requirement listed in the following table.

Step	**N2O flow (L/min)**	**O2 flow (L/min)**
1	7.5	≥2.0
2	3.0	≥0.8
3	1.5	≥0.4
4	0.6	≥0.2

7. Disconnect the O_2 pipeline supply or close the O_2 cylinder valve.

NOTE

- **When O_2 supply is disconnected, alarms for [O2 Supply Failure] and [Drive Gas Pressure Low] occur as O_2 pressure decreases.**

8. Set the system switch to the ⏻ position.

6.7.2 With O2 Concentration Monitoring

Do as described in ***6.9.2*** before testing. To do the flow control system tests:

1. Connect the pipeline supplies or slowly open the cylinder valves.
2. Turn all flow controls fully clockwise (minimum flow).
3. Set the system switch to the ⊙ position.
4. Do not use the system if low battery or other ventilator failure alarms occur.

Steps 5 and 6 are only for systems with N_2O.

⚠WARNING

- **During steps 5 and 6, the O_2 sensor used must be correctly calibrated and the Link system should be kept engaged.**
- **Adjust only the test control (N_2O in step 5 and O_2 in step 6).**
- **Test the flows in sequence (N_2O then O_2).**

5. Test the O_2-N_2O Link system with flow increasing:
   - Turn the N_2O and O_2 flow controls fully clockwise (minimum flow).
   - Slowly turn the N_2O flow control counterclockwise.
   - Make sure that the O_2 flow increases. The measured O_2 concentration must be ≥21% through the full range.
6. Test the O_2-N_2O Link system with flow decreasing:
   - Turn the N_2O flow control and set the N_2O flow to 9.0 L/min.
   - Turn the O_2 flow control and set the O_2 flow to 3 L/min or higher.
   - Slowly turn the O_2 flow control clockwise.
   - Make sure that the N_2O flow decreases. The measured O_2 concentration must be ≥21% through the full range.
7. Adjust the flow of all gases through their full range and make sure that the flowtube floats move smoothly.
8. Disconnect the O_2 pipeline supply or close the O_2 cylinder valve.
9. Make sure that:
   - N_2O and O_2 flows stop. The O_2 flow stops last.
   - Air flow continues if Air supply is available.
   - Gas supply alarms occur on the ventilator.

10. Turn all the flow controls fully clockwise (minimum flow).
11. Reconnect the O_2 pipeline supply or open the O_2 cylinder valve.
12. Set the system to Standby.

6.8 Vaporizer Back Pressure Test

⚠WARNING

- **Use the Selectatec@ series vaporizers only. Make sure that the vaporizers are locked when doing the test.**
- **During the test, the anesthetic agent comes out of the fresh gas outlet. Use a safe and approved procedure to remove and collect the agent.**
- **To prevent damage, turn the flow controls fully clockwise (minimum flow or OFF) before using the system.**

Before the test, make sure that the vaporizers are correctly installed. For details about vaporizer installation, refer to ***10.4Install the Vaporizer.***

1. Connect the O_2 pipeline supply or open the O_2 cylinder valve.
2. Turn the O_2 flow control and set the O_2 flow to 6 L/min.
3. Make sure that the O_2 flow stays constant.
4. Adjust the vaporizer concentration from 0 to 1%. Make sure that the O_2 flow must not decrease more than 1 L/min through the full range. Otherwise, install a different vaporizer and try this step again. If the problem persists, the malfunction is in the anesthesia system. Do not use this system.
5. Test each vaporizer as per the steps above.

NOTE

- **Do not perform test on the vaporizer when the concentration control is between "OFF" and the first graduation above "0" (zero) as the amount of anesthetic drug outputted is very small within this range.**

6.9 Breathing System Tests

⚠WARNING

- **Objects in the breathing system can stop gas flow to the patient. This can cause injury or death. Make sure that there are no test plugs or other objects in the breathing system.**
- **Do not use a test plug that is small enough to fall into the breathing system.**

1. Make sure that the breathing system is correctly connected and not damaged.
2. Make sure that the check valves in the breathing system work correctly:
   - The inspiratory check valve opens during inspiration and closes at the start of expiration.
   - The expiratory check valve opens during expiration and closes at the start of inspiration.

6.9.1 Bellows Test

1. Set the system to Standby.
2. Set the bag/mechanical ventilation switch to the mechanical ventilation position.
3. Set all flow controls to minimum.
4. Connect the Y piece on the breathing tube to the leak test plug on the breathing system. Occlude the gas outlet of the Y piece.
5. Push the O_2 flush button to fill the bellows, which rises to the top.
6. Make sure that the pressure must not increase to more than 15 cmH_2O on the airway pressure gauge.
7. The bellows should not fall. If it falls, it has a leak. You need to reinstall the bellows.

6.9.2 Breathing System Leak Test in Manual Ventilation Status

NOTE

- **Leak test must be performed when the system is in standby status.**
- **Before doing the leak test, make sure that the breathing system is correctly connected and the breathing tubes not damaged.**

1. Make sure that the system is Standby. If not, press the ⏻ key and select [**Ok**] from the pop-up menu to enter standby status.
2. Connect the Y piece on the breathing tube to the leak test plug on the breathing system.
3. Turn the APL valve control to 75 cmH_2O.
4. Connect the manual bag to the manual bag port.
5. Adjust all flow controls to zero.
6. Make sure that the bag/mechanical ventilation switch is at the bag position.
7. Push the O_2 flush button to produce pressure of 25 to 35 cmH_2O displayed on the airway pressure gauge.
8. Verify that the bellows remain unmoved when the above step is performed. Otherwise, contact us or your service personnel.
9. Select [**Maintenance**] hot key and select [**System Leak&Compliance Test**] to enter the manual circuit leak test screen.
10. Select [**Continue**] to start leak test. After the test is completed, the system displays the relevant prompt message. Operate following the relevant prompt message.

6.9.3 Breathing System Leak Test in Mechanical Ventilation Status

NOTE

- **Leak test must be performed when the system is in standby status.**
- **Before doing the leak test, make sure that the breathing system is correctly connected and the breathing tubes not damaged.**

1. Make sure that the system is Standby. If not, press the ⏻ key and select [**Ok**] from the pop-up menu to enter standby status.
2. Connect the Y piece on the breathing tube to the leak test plug on the breathing system.
3. Adjust all flow controls to zero.
4. Make sure that the bag/mechanical ventilation switch is at mechanical ventilation position.

5. Push the O_2 flush button to fill the bellows, which rises to the top
6. Select [**Maintenance**] hot key and select [**System Leak&Compliance Test**] to enter the manual circuit leak test screen.
7. Select [**Skip**] to go to the auto circuit leak test screen.
8. Select [**Continue**] to start leak/compliance test. After the test is completed, the system displays the relevant prompt message. Operate following the relevant prompt message.

NOTE

- **In case of leak test failure, check all possible leak sources, including bellows, breathing tubes, and CO2 absorbent canister. Check that they are correctly connected and their connectors are undamaged. When checking the CO2 absorbent canister, check if there is absorbent attaching the sealing component of the canister. If there is, clear the absorbent**
- **Do not use the anesthesia machine if breathing system leak occurs. Contact your service personnel or us.**

6.9.4 APL Valve Test

1. Make sure that the system is Standby. If not, press the ⏻ key and select [**Ok**] from the pop-up menu to enter Standby.
2. Set the bag/mechanical ventilation switch to the bag position.
3. Connect the manual bag to the manual bag port.
4. Connect the Y piece on the breathing tube to the leak test plug.
5. Turn the APL valve control to let the pressure of APL valve stay at 30 cmH_2O.
6. Push the O2 flush button to inflate the manual bag.
7. Make sure that the reading on the airway pressure gauge is with the range of 20 to 40 cmH_2O.
8. Turn the APL valve control to the MIN position.
9. Set the O_2 flow to 3 L/min. Turn any other gases off.
10. Make sure that the reading on the airway pressure gauge is less than 5 cmH_2O.
11. Push the O_2 flush button. Make sure that the reading on the airway pressure gauge does not exceed 10 cmH2O.
12. Turn the O_2 flow control to set the O_2 flow to minimum. Make sure that the reading on the airway pressure gauge does not decrease below 0 cmH_2O.

9.5.4 Set CO2 Unit

In the [**Gas Module Setup >>**] menu, select [**CO2 Unit**] and toggle between [**mmHg**], [**%**], and [**kPa**].

9.5.5 Set Patient Age

Set [**Patient Age (years)**] to an appropriate value in the [**Gas Module Setup >>**] menu.

9.5.6 Restore Defaults

Select [**Defaults**] from the [**Gas Module Setup**] menu. Then all the options in this menu except [**Working Mode**] are restored to the factory default configurations.

9.5.7 Set CO2 Waveform

1. Select the waveform area, open the corresponding menu.
2. Select [**CO2**] for [**Waveform**].
3. Select [**Sweep**] and set waveform sweep speed to an appropriate value. The greater the value is set to, the faster the waveform sweeps, the wider the waveform is.
4. Select ☒ to exit the current menu.

For details about displaying the CO_2 waveform, refer to ***5.3.3.2 Display CO2 Waveform.***

9.6 Change Anesthetic Agent

If the anesthetic agent used changes, the AG module is capable of detecting the gas mixture during the transition period. The time required for anesthetic agent exchange depends upon the type of anesthesia (low flow or high flow) and the features of the anesthetic agents used (pharmacokinetics). During the exchange, the anesthesia machine gives no prompt message and the MAC values displayed may be inaccurate.

The AG module can identify anesthetic agent automatically. When one anesthetic agent decreases below the threshold value and another anesthetic agent plays the dominant role, the anesthesia machine can identify such exchange automatically and displays the name and data of the dominant anesthetic agent.

B.9 Anesthetic Vaporizer

Anesthetic vaporizer (for details, refer to the vaporizer Instructions for Use)	
Type	Penlon Sigma Delta or Sigma Alpha anesthetic vaporizers. Five types of vaporizers with anesthetic agents halothane, enflurane, isoflurane, sevoflurane, desflurane are available. Mindray-made V60 vaporizer. Four types of anesthetic agents are optional, which are Enflurane, isofluane, halothane, and sevoflurane.
Selectatec® vaporizer manifold	
Vaporizer position	Single or double vaporizer positions (optional)
Mounting mode	Selectatec®, with interlocking function (Selectatec® is registered trademark of Datex-Ohmeda Inc.)
Plug-in® vaporizer manifold	
Vaporizer position	double vaporizer positions
Mounting mode	Plug-in ®, with interlocking function

	Sev	0 to 1	±0.15
		1 to 5	±0.2
		5 to 8	±0.4
		＞8	Not specified
	Enf, Iso, Hal	0 to 1	±0.15
		1 to 5	±0.2
		＞5	Not specified
Rise time*	CO_2	≤250 ms	
	N_2O	≤250 ms	
	O_2	≤500 ms	
	Enf	≤350 ms	
	Des, Sev, Iso, Hal	≤300 ms	
Delay time	＜4 s		
Update time	Once per second		
Calibration	Once per year		
Calibration stability	<1% to inaccuracy after continuous use of 12 months.		

*： 10% to 90%. Sample gas flow: 200 mL/min. DRYLINETM watertrap. Adult DRYLINETM sampling line (2.5 m).

AG alarm limits	Range	Step	Unit
EtCO2 High Limit	(low limit + 2) to 76	1	mmHg
EtCO2 Low Limit	0 to (high limit – 2)		
FiCO2 High Limit	(low limit + 2) to 76		
FiCO2 Low Limit	0 to (high limit – 2)		
EtN2O High Limit	(low limit + 2) to 100	1	%
EtN2O Low Limit	0 to (high limit – 2)		
FiN2O High Limit	(low limit + 2) to 100		
FiN2O Low Limit	0 to (high limit – 2)		
EtHal High Limit	(low limit + 0.2) to 5.0	0.1	%
EtHal Low Limit	0.0 to (high limit – 0.2)		
FiHal High Limit	(low limit + 0.2) to 5.0		
FiHal Low Limit	0.0 to (high limit – 0.2)		
EtEnf High Limit	(low limit + 0.2) to 5.0	0.1	%
EtEnf Low Limit	0.0 to (high limit – 0.2)		
FiEnf High Limit	(low limit + 0.2) to 5.0		
FiEnf Low Limit	0.0 to (high limit – 0.2)		
EtIso High Limit	(low limit + 0.2) to 5.0	0.1	%
EtIso Low Limit	0.0 to (high limit – 0.2)		
FiIso High Limit	(low limit + 0.2) to 5.0		