WATO EX-65

Anesthesia System

Operator’s Manual

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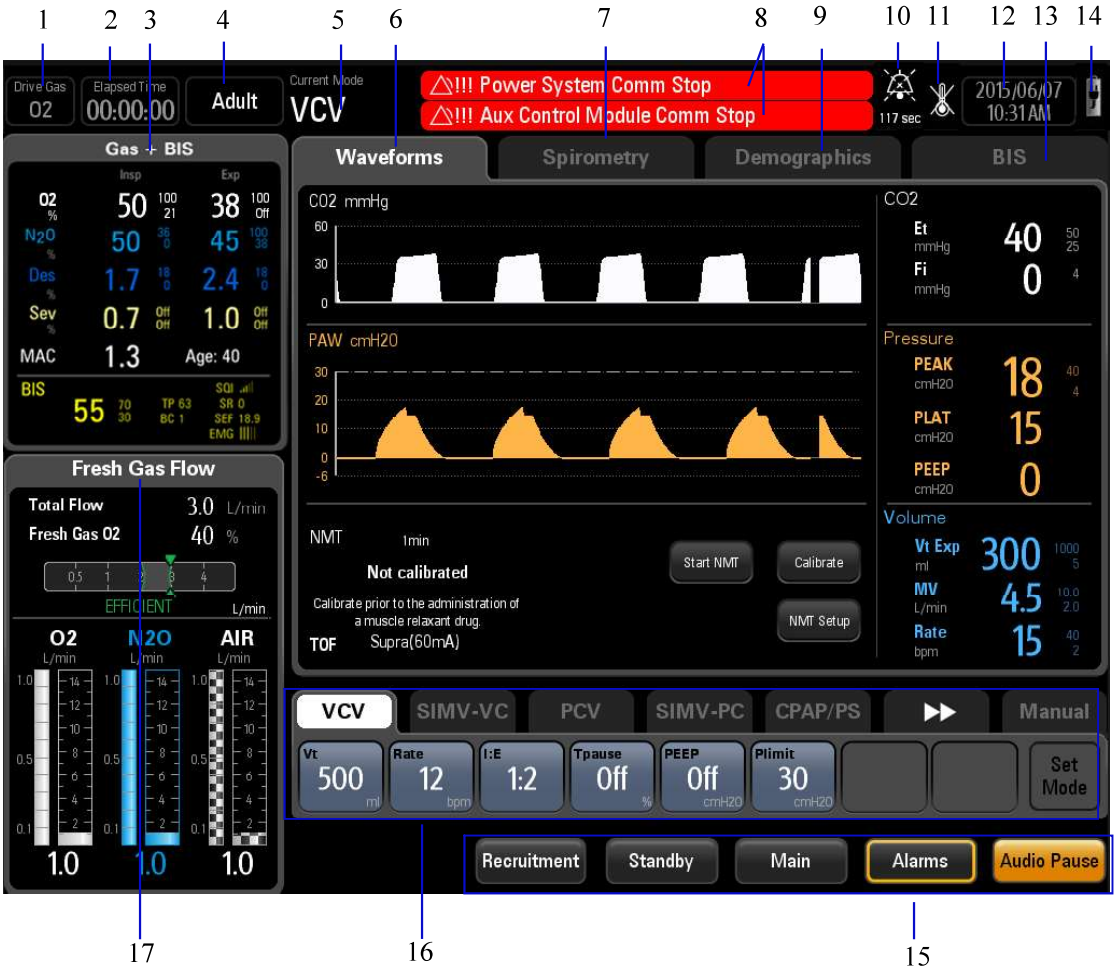
3 System Controls and Basic Settings

3.1 Display Control



1. Drive Gas

   Displayed if configured with Drive Gas Auto Switch function. It displays current drive gas type. When the primary drive gas pressure is low and the temporary drive gas pressure is normal, select [**Yes**] from the pop-up dialog box to switch to the temporary drive gas. When the primary drive gas pressure resumes, select [**Yes**] from the pop-up dialog box to switch to the primary drive gas. When the area displays the temporary drive gas or the primary drive gas pressure is low, you can select the area to open the [**Drive Gas**] menu and set the drive gas in the menu.

2. Elapsed Timer

   Displays elapsed time. Select to start, stop, or reset the timer.

3. Gas and/or BIS Area

   Displayed when AG module and/or BIS module is connected. It displays real-time inspiratory and expiratory levels of gas concentration.

6 Preoperative Test

6.1 Preoperative Test Schedules

Perform the preoperative tests listed below at these events:

1. When required after a maintenance or service procedure.
2. Every day before the first patient.
3. Before each patient.

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	
Inspect the negative pressure suction device	

NOTE

- **Read and understand the operation and maintenance of each component before using the anesthesia system.**
- **Do not use the anesthesia system 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

- **Ensure that the breathing system is correctly connected and not damaged.**

Perform the following inspection checklist before operating the system:

1. The anesthesia system is correctly connected and undamaged.
2. Inspect the system for:
   a. Damage to flowmeters, vaporizers, gauges, and supply hoses
   b. Complete breathing system with adequate Pre-Pak or loose fill CO_2 absorbent
   c. Correct mounting of cylinders in yokes
   d. Presence of cylinder wrench
   e. Auxiliary O_2 supply, available and functioning
3. Check that:
   a. Flow-control valves are off
   b. Vaporizers are off
   c. Vaporizers are filled (not overfilled)
   d. Filler caps are sealed tightly
   e. Two vaporizers cannot be turned on at the same time
4. All components are correctly attached.
5. The breathing system is correctly connected, the breathing tubes are undamaged, and the self-inflating manual ventilation device is available and functioning.
6. The gas supplies are connected and the pressures are correct.
7. Cylinder valves are closed on models with cylinder supplies (Verify that the cylinder wrench is attached.).
8. The necessary emergency equipment is available and in good condition.
9. Equipment for airway maintenance and tracheal intubation is available and in good condition.
10. Inspect the color of the absorbent in the canister. Replace the absorbent immediately if obvious color change is detected.

⚠WARNING

- **Check if the gasket is properly installed in place while installing the absorbent canister. If the gasket is not properly installed (for example, gasket is not evenly seated and centered) it may cause breathing system leakage.**

11. Applicable anesthetic and emergency drugs are available.
12. The casters are not damaged or loose and the brake (s) is set and prevents movement.
13. Ensure the breathing system is proper position.
14. The AC mains indicator and the battery indicator are displayed when the power cord is connected to the AC power source. If the indicators are not displayed, the system does not have electrical power.
15. The anesthesia system is switched on or off normally.

6.3 System Self- Test

When the system is powered on, it performs a self-test to ensure its alarm system (alarm LED, speaker, and buzzer) and hardware (flowmeter board, ventilator board, assistant ventilator board, power board, and CPU board) are properly functioning.

1. Turn the power switch on the front panel to the  position. The system powers up and begins its system self-test.

   After the system self-test is completed, the test results are displayed on the screen. Startup alarm messages also may be displayed.
2. Proceed to operate or troubleshoot the system based on the self-test results.

6.4 Leak and Compliance Tests

6.4.1 Automatic Circuit Leak and Compliance Test

NOTE

- **The system records the result of the last Automatic Circuit Leak & Compliance Test in the [General] tab, including if the test had passed, failed, or was skipped. To access this information, from the main screen, select the** [Main] **softkey → [General] tab.**
- **If fresh gas is detected by the system before proceeding with the Automatic Circuit Leak & Compliance Test, a [Fresh gas flow detected! Adjust all flowmeters to zero].**

1. Start to test.

■ From power up:

If the System is being powered on, the system automatically initiates a self-test and enters the [**Automatic Circuit Leak & Compliance Test**] screen, followed by the [**Manual Circuit Leak Test**] screen. If the [**Skip**] button is selected, the system bypasses the [**Automatic Circuit Leak & Compliance Test**] and the [**Manual Circuit Leak Test**] and enters the Standby screen.

■ From the main screen:

Select the **[Main]** softkey → [**General**] tab → [**Test Leak/Compliance**] button.

2. Follow the instructions on the screen:
   (1) Seal the Y-piece.
   (2) Ensure that the sample line port of the breathing circuit is occluded.
   (3) Install the manual bag.
   (4) Adjust all flowmeters to zero.
   (5) Set the Auto/Manual switch to the  position
   (6) Press the O_2 flush button to completely fill the bellows.
   (7) Select [**Continue]** button to proceed with the Automatic Circuit Leak Test.

NOTE

- **The [Continue] button can be selected only when the Auto/Manual switch is set to the  position and when no fresh gas is detected.**

3. Proceed to operate based on the self-test results.

6.4.2 Manual Circuit Leak Test

NOTE

- **If fresh gas is detected by the system before proceeding with the Manual Circuit Leak Test, a [Fresh gas flow detected! Adjust all flowmeters to zero] message is displayed on the screen.**

1. Start to test.

■ From power up:

If the System is being powered on, the system automatically initiates a self-test followed by Automatic Circuit Leak and Compliance Test and the Manual Circuit Leak Test. If the [**Skip**] button is selected, the system bypasses these tests and enters the Standby screen.

■ From the main screen:

Select the **[Main]** softkey → [**General**] tab → [**Test Leak/Compliance**] button.

2. Follow the instructions on the screen:
   (1) Adjust the **APL** to the 50 cmH_2O position.
   (2) Adjust all flowmeters to zero.
   (3) Set the Auto/Manual switch to the  position.
   (4) Press the O_2 flush button until the airway pressure gauge value is between 25 and 35 cmH_2O.
   (5) Select [**Continue**] button to proceed with the **Manual Circuit Leak Test**.
   Or, Select [**Skip**] button to go directly to operational mode.

NOTE

- **The [Continue] button can be selected only when the Auto/Manual switch is set to the  position and when no fresh gas is detected.**

3. Proceed to operate based on the self-test results.

6.5 Power Failure Alarm Test

1. Set the system switch to the  position.
2. Disconnect the AC mains.
3. Ensure that the AC mains indicator and battery charge indicator are extinguished. An audible alarm should sound and the prompt message [**Battery in Use**] should be displayed on the main screen.
4. Reconnect the AC mains.
5. Ensure that an audible alarm should sound and the AC mains indicator and battery charge indicator are illuminated. The prompt message [**Battery in Use**] should not be displayed on the main screen.
6. Set the system switch to the  position.

6.6 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.**

6.6.1 O_2 Pipeline Test

1. Connect the O_2 pipeline supply.
2. Close all cylinder valves if the anesthesia system is equipped with cylinders.
3. Set the system switch to the  position.
4. Set the O_2 flow to 6 L/min.
5. Ensure that O_2 pipeline pressure gauges show 280 to 600 kPa (40 to 87 psi).
6. Disconnect the O_2 supply.
7. As O_2 pressure decreases, alarms for [**O_2 Supply Failure**] and [**Drive Gas Pressure Low**] should occur.
8. Ensure that the O_2 gauge goes to zero.

6.6.2 N_2O Pipeline Test

NOTE

- **When doing the N_2O pipeline test, connect O_2 supply first to enable N_2O flow control.**
- **When N_2O supply is disconnected, alarms related to N_2O pressure occur as N_2O pressure decreases.**
- **Use a safe and approved procedure to collect and remove N2O gas.**

1. Connect the O_2 and N_2O pipeline supplies.
2. Close all cylinder valves if the anesthesia system is equipped with cylinders.
3. Set the system switch to the  position.
4. Set the O_2 flow to 3L/min.
5. Set the N_2O flow to 6 L/min.
6. Check that the N_2O pipeline pressure gauges show 280 to 600 kPa (40 to 87 psi).
7. Disconnect the N_2O pipeline supply.
8. As N_2O pressure decreases, alarms for [**N_2O Supply Failure**] should occur.
9. Ensure that the N_2O gauge decreases to zero.

6.6.3 Air Pipeline Test

NOTE

- **When Air supply is disconnected, alarms related to Air pressure occur as Air pressure decreases.**

1. Connect the Air pipeline supply.
2. Close all cylinder valves if the anesthesia system is equipped with cylinders.
3. Set the system switch to the  position.
4. Set the Air flow to 6 L/min.
5. Check that the Air pipeline pressure gauges show 280 to 600 kPa (40 to 87 psi).
6. Disconnect the Air pipeline supply.
7. As Air pressure decreases, alarms for [**Air Supply Failure**] should occur.
8. Ensure that the Air gauge decreases to zero.

6.7 Basic Ventilation Test

1. Attach a breathing circuit and breathing bag.
2. Attach an adult test lung or breathing bag to the patient end of the Y-fitting of the breathing circuit.
3. Set the O_2 flow to 3 L/min and set the N_2O and Air flow rates to zero flow.
4. Set the ventilator controls to:

Ventilator Controls	Ventilator Settings
Patient Type	Adult
Ventilation Mode	PCV
Pressure control level of inspiration - Pinsp	20
Breath rate – Rate	8
I:E Ratio - I:E	1:2
Positive end-expiratory pressure - PEEP	OFF
Time for the pressure to rise to target pressure - Tslope	0.5

5. Select PCV and begin ventilation.
6. Verify that the breathing bag at the patient end of the Y-fitting of the breathing circuit inflates and deflates and that the PLAT on the display and the airway pressure gauge are consistent with the Pinsp setting.

6.8 Cylinder Tests

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

6.8.1 Check the Cylinder Pressure

1. Set the system switch to the  position and connect the cylinders to be checked.
2. Slowly open each cylinder valve using the supplied wrench.
3. Ensure that each cylinder has sufficient pressure. If not, close the applicable cylinder valve and install a full cylinder.
4. Close all cylinder valves.

6.8.2 O_2 Cylinder High Pressure Leak Test

1. Set the system switch to the  position and disconnect O_2 pipeline supply.
2. Turn off the O_2 flowmeter.
3. Slowly 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.
7. If the cylinder pressure decreases more than 5000 kPa (725 psi), install a new cylinder gasket. Repeat steps 1 through 6. If the leak continues, do not use the cylinder supply system.

6.8.3 N_2O Cylinder High Pressure Leak Test

1. Set the system switch to the  position and disconnect N_2O pipeline supply.
2. Turn off the N_2O flowmeter.
3. Slowly open the N_2O cylinder valve.
4. Record the current cylinder pressure.
5. Close the N_2O cylinder valve.
6. Record the cylinder pressure after one minute.
7. If the cylinder pressure decreases more than 700 kPa (100 psi), install a new cylinder gasket. Repeat steps 1 through 6. If the leak continues, do not use the cylinder supply system.

6.8.4 Air Cylinder High Pressure Leak Test

1. Set the system switch to the  position and disconnect Air pipeline supply.
2. Turn off the Air flowmeter.
3. Slowly open the Air cylinder valve.
4. Record the current cylinder pressure.
5. Close the Air cylinder valve.
6. Record the cylinder pressure after one minute.

7. If the cylinder pressure decreases more than 5000 kPa (725 psi), install a new cylinder gasket. Repeat steps 1 through 6. If the leak continues, do not use the cylinder supply system.

6.9 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 inlet.
2. Set the system switch to  .
3. Slowly 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. Ensure 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 [**O_2 Supply Failure**] alarm and [**Drive Gas Pressure Low**] alarm will be triggered.
8. Ensure that the value of the oxygen pipeline pressure gauge is back to zero.

6.10 Flow Control System Tests

6.10.1 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 N_2O gas.**
- **Incorrect gas mixtures can cause patient injury. If the O_2:N_2O ratio 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 use excessive force on the flow controls. After performing the cylinder tests, close all cylinder valves if cylinder supplies are not used.**
- **Turn the flow controls slowly. To avoid damaging the control valves, do not turn further when the flowmeter reading is outside the range. When turning a flow control knob clockwise to decrease flow, the flowmeter should reach zero before the knob reaches its most clockwise mechanical stop (Off) position. Do not turn any further when the knob has reached the Off position. Similarly, when turning a flow control knob counterclockwise to increase flow from zero, the flowmeter reading should not indicate a change from zero until the flow control knob is turned approximately one (1) rotation counterclockwise from the Off position, and only if permitted according to the gas ratio control system.**
- **N2O is cutoff when O2 supply is less than 100 kPa.**

To perform the flow control system tests:

1. Connect the pipeline supplies or slowly open the cylinder valves.
2. Turn all flow controls fully clockwise (flow OFF).
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 ratio 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	N_2O flow (L/min)	O_2 flow (L/min)
1	0.9	≥0.3
2	1.5	≥0.5
3	3.0	≥1.0
4	6.0	≥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	N_2O flow (L/min)	O_2 flow (L/min)
1	6.0	≥2.0
2	3.0	≥1.0
3	1.5	≥0.5
4	0.9	≥0.3

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

NOTE

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

8. Set the system switch to the ○ position.

6.10.2 With O2 Concentration Monitoring

Do as described in ***6.13.2 Test the O2 Concentration Monitoring and Alarms*** 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.

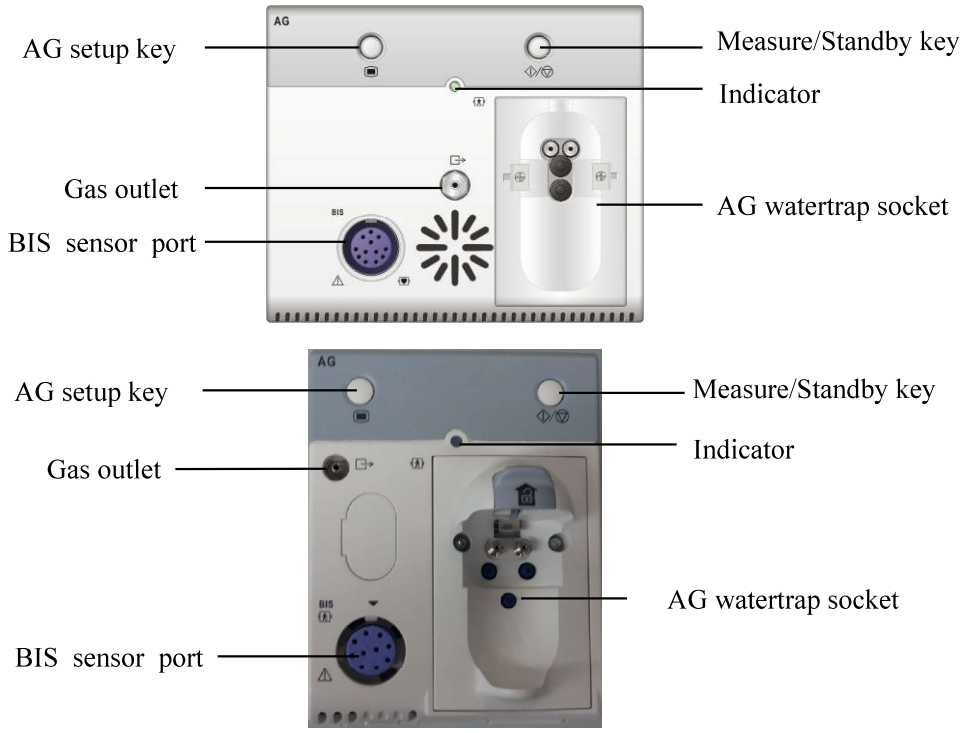
   Steps 5 and 6 are only for systems with N_2O.

⚠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).**

9.4 Identify AG Modules

The AG module can identify anesthesia gas automatically.



For information about BIS module, see ***10 BIS Monitoring***.

NOTE

- **The AG module is configured with the function of compensating barometric pressure automatically.**

9.5 Prepare to Measure AG

1. Select the appropriate watertrap according to patient type and attach it to the watertrap socket.
2. Connect one end of the gas sampling tube to the watertrap.
3. Connect the other end of the gas sampling tube to the patient tubing via the airway adapter.

AGSS receiving hosing, (35G-WAGD-DS/FG2-3), from AGSS assembly to vacuum system	082-001372-00
AGSS British-standard connection material kit	115-020745-00
AGSS kit, low flow, high vacuum	115-030332-00
AGSS kit, high flow, low vacuum	115-030333-00
AGSS Assembly, high-flow, low vacuum	115-017375-00
AGSS Assembly, low-flow, high vacuum	115-017376-00
Patient Monitor Bracket Assembly	
Top shelf mounting kit for Beneview T5	115-004004-00
Top shelf mounting kit for Beneview T8	115-004003-00
GCX bracket kit for monitor PM7000, 8000	115-015769-00
GCX bracket kit for Beneview T5, PM 9000	115-015770-00
GCX bracket kit for Beneview T8	115-015783-00
GCX bracket kit for Beneview T5, with module rack mounting pole	115-015771-00
GCX bracket kit for Beneview T8, with module rack mounting pole	115-015784-00
GCX bracket kit for iMEC, iPM	115-015786-00
GCX Bracket for N12/15/17/ePM15, fixed height	115-066028-00
GCX Bracket for N12/15/17, variable	115-066029-00
GCX Bracket for ePM10/12/uMEC, fixed height	115-070011-00
GCX Bracket for ePM10/12/uMEC, variable height	115-070768-00
Top shelf mounting kit for N15/17	115-070794-00
Top shelf mounting kit for N12	115-074073-00
GCX external auxiliary work surface	115-073384-00
Flexible bag arm assembly	115-048035-00
Gas Source Hose	
O2 supply hose, British standard, NIST, 5m, 34I-OXY-BS/NS-5	082-001209-00
Air supply hose, British standard, NIST, 5m, 34I-AIR-BS/NS-5	082-001210-00
N2O supply hose, British standard, NIST, 5m, 34I-N2O-BS/NS-5	082-001211-00
O2 supply hose, Germany standard, NIST, 5m, 34I-OXY-GS/NS-5	082-001212-00
Air supply hose, Germany standard, NIST, 5m, 34I-AIR-GS/NS-5	082-001213-00
N2O supply hose, Germany standard, NIST, 5m, 34I-N2O-GS/NS-5	082-001214-00
O2 supply hose, Australian standard, NIST, 5m, 34I-OXY-SIS/NS-5	082-001215-00
Air supply hose, Australian standard, NIST, 5m, 34I-AIR-SIS/NS-5	082-001216-00
N2O supply hose, Australian standard, NIST, 5m, 34I-N2O-SIS/NS-5	082-001217-00
O2 supply hose, French standard, NIST, 5m, 34I-OXY-FS/NS-5	082-001218-00
Air supply hose, French standard, NIST, 5m, 34I-AIR-FS/NS-5	082-001219-00
N2O supply hose, French standard, NIST, 5m, 34I-N2O-FS/NS-5	082-001220-00
O2 supply hose, US standard, DISS, 5m, 34U-OXY-DS/DS-5	082-003443-00
N2O supply hose, US standard, DISS, 5m, 34U-N2O-DS/DS-5	082-003444-00
Air supply hose, US standard, DISS, 5m, 34U-AIR-DS/DS-5	082-003445-00
O2 supply hose, British Standard, DISS, 5m, 34U-OXY-BS/DS-5	082-001227-00
Air supply hose, British Standard, DISS, 5m, 34U-AIR-BS/DS-5	082-001228-00

B.10 Anesthetic Vaporizer

Anesthetic vaporizer (for details, refer to the vaporizer Instructions for Use)	
Type	Penlon Sigma Delta anesthetic vaporizers. Four types of vaporizers with anesthetic agents Halothane, Enflurane, Isoflurane, and Sevoflurane are available. Mindray V60 vaporizer. Four types of anesthetic agents are available, which are Halothane, Enflurane, Isofluane, and Sevoflurane. Drager D-Vapor Desflurane vaporizer
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

B.11 Breathing System Temperature Controller

In the range of 10° C≤T ambient≤20° C, the temperature at the middle plate test point near the inspiratory check valve shall be a minimum ΔT of 11° C above the ambient temperature.

In the range of 20° C≤T ambient≤40° C, the temperature at the middle plate test point near the inspiratory check valve shall be a minimum of 31° C.

In the range of 10° C≤T ambient≤40° C, the temperature at the Y-piece patient connection test point shall be a maximum absolute value of ΔT of 2° C above the ambient temperature and the temperature at the Y-piece patient connection test point shall be a maximum of 41° C.

Under the single fault condition, the temperature at the Y-piece patient connection test point shall be a maximum of 41° C.

threshold[7]	primary agent >10%	5% $_{REL}$ (10% $_{REL}$ for Isoflurane) of primary agent

AG alarm limits	Range	Step	Unit
$EtCO_2$ High Limit	OFF, (low limit + 2) to 99	1	mmHg
$EtCO_2$ Low Limit	OFF, 0 to (high limit – 2)		
$FiCO_2$ High Limit	OFF, 1 to 99		
EtN_2O High Limit	OFF, (low limit + 2) to 100	1	%
EtN_2O Low Limit	OFF, 0 to (high limit – 2)		
FiN_2O High Limit	OFF, (low limit + 2) to 100		
FiN_2O Low Limit	OFF, 0 to (high limit – 2)		
EtHal High Limit	OFF, (low limit + 0.2) to 5.0	0.1	%
EtHal Low Limit	OFF, 0.0 to (high limit – 0.2)		
FiHal High Limit	OFF, (low limit + 0.2) to 5.0		
FiHal Low Limit	OFF, 0.0 to (high limit – 0.2)		
EtEnf High Limit	OFF, (low limit + 0.2) to 5.0	0.1	%
EtEnf Low Limit	OFF, 0.0 to (high limit – 0.2)		
FiEnf High Limit	OFF, (low limit + 0.2) to 5.0		
FiEnf Low Limit	OFF, 0.0 to (high limit – 0.2)		
EtIso High Limit	OFF, (low limit + 0.2) to 5.0	0.1	%
EtIso Low Limit	OFF, 0.0 to (high limit – 0.2)		
FiIso High Limit	OFF, (low limit + 0.2) to 5.0		
FiIso Low Limit	OFF, 0.0 to (high limit – 0.2)		
EtSev High Limit	OFF, (low limit + 0.2) to 8.0	0.1	%
EtSev Low Limit	OFF, 0.0 to (high limit – 0.2)		
FiSev High Limit	OFF, (low limit + 0.2) to 8.0		
FiSev Low Limit	OFF, 0.0 to (high limit – 0.2)		
EtDes High Limit	OFF, (low limit + 0.2) to 18.0	0.1	%
EtDes Low Limit	OFF, 0.0 to (high limit – 0.2)		
FiDes High Limit	OFF, (low limit + 0.2) to 18.0		
FiDes Low Limit	OFF, 0.0 to (high limit – 0.2)		
MAC High Limit	OFF, (low limit + 0.2) to 12.0	0.1	/
MAC Low Limit	OFF, 0.0 to (high limit – 0.2)		

Effect of interfering gas on AG measured value

[7] For Halothane: Increase in threshold by 0.1%$_{ABS}$.