Western Surgical®

ALPHA FLATOR 25D

Microprocessor Based High Digital Co2 Insufflator

USER MANUAL

www.westernsurgical.in
Email : westernsurgical@gmail.com
Email : info@westernsurgical.in
Ph. : +91-281-2232871 / 2243159

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Microprocessor Based High Flow

Digital Co2 Insufflator

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OM SURGICALS®

The Surgical Innovative House

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- Prior to operating the device, check the device completely to ensure that it is working properly and it is not damaged in any way.
- In order to avoid either damaging the device through improper assembly/operation or en danger the manufacturers liability. Use the product exactly as indicated in these instructions for use. Follow the safety and maintenance instruction. Only combine OM SURGICALS product with each other.
- Only allow persons to use the product and its accessories who possess the requisite training, knowledge and experience to do so.
- Keep the instructions for use to all operating room staff.
- Ensure that the electrical facilities in the room in which the device is being used confirms to ICE norms.
- Unplug the device by pulling out the plug from the device.
- Do not use device within demarcated hazard zones! (Explosive gases).
- Make sure that the ambient temperature does not exceed 35°c.

⚠ Warnings

- This unit is used whenever laparoscopy is indicated. This unit can be operated by qualified persons who have been trained in its use. Endoscopic instruments and equipment may only be used by physicians who have completed appropriate training. Carefully study this manual before initial operation. Do not use this unit for distension of the uterine cavity (hysteroscopy). There`s always exists a danger of embolism. Do not use the device with in demarcated hazard zones! (Explosive gases). Follow the required procedures for sterile conditions.
- In case of unfavorable conditions during the operation (high leakage rate, high gas flow, and long operation time) make sure that the patient does not suffer from hypothermia. In case of a high gas flow during the operation immediately check the system for leakage. Leakages in the path of insufflation (tubing connection opened etc……) can cause harm to the patient!
- Do not exceed 20mmHg patient pressure. Sustained patient pressure above 20mmHg with Co2 may result in depression of patient cardiopulmonary system. Always operate device at or above patient`s height to prevent patient syphoning or back flow of bodily fluids, saline etc… Use only liquefied medical grade Co2 at full concentration. Mixtures of gases, high pressure liquefied gas penetrates the internal unit! This can cause freezing and the output of gas will be reduced. Always keep the Co2 tank in an upright position! Never use a bottle with integrated standpipe!

- Please read carefully this manual before using the device for the first time.
- You prevent yourself from damages, which occur through wrong connections or improper operation.
- Use the insufflator only for purposes described in this manual.
- No liability for damages caused by misuse of the device.
- This manual does not contain any detailed description of endoscopic procedures and is not suitable for a beginner to maintain endoscopic interventions.

- EMBOLISM: Can be caused through improper placement of the insufflation instruments. (Gas penetrates into a vessel). Avoid high intra-abdominal pressure. Attention! Check the correct position of the insufflation instruments.

- GAS FLOW: High gas flow rates can be caused by leakages. Please check immediately the device, tube and instruments.
- Co2 ABSORPTION: The body absorbs a part of the Co2 gas. Which are too high may result in serious injury or death of the patient!
  During insufflation process always monitor the patient's vital function and take care of sufficient respiration. Pressure values above 15mmHg are required only for a few cases but increases the risk of intravastion.
  Metabolic and Cardiac reactions. A pressure of more than 20mmHg may result in metabolic acidosis.
- IDIOSYNCRATION REACTIONS: Patients with sickle cell anemia or pulmonary insufficiency may have a higher risk of metabolic imbalance related to excessive Co2 absorption (idiosyncratic reaction).
- HYPOTHERMAL: During insufflation high gas flow will result in a lower body temperature. Avoid hypothermia of the patient. Dehydration has to be avoided as well.
- Co2 supply: Use only medical grade Co2. Always have a filled Co2 cylinder ready for replacement.

1. INTENDED USE

Device to insufflate Co2 gas into the abdomen during laparoscopy (diagnostic & surgical laparoscopic procedures). In order to obtain high visibility conditions and sufficient space for endoscopic procedures, the body cavity has to be dilated with Co2.

1.1 FUNCTION

The insufflator described in this manual incorporates the latest technological safety standards and offers two different types of insufflation modes as follows :

DEFAULT MODE: (i.e low flow insufflation mode). The insufflation pressure is achieved by setting the flow at an optimum level (i.e.3LPM). This allows the users to determine and to know the level of max insufflation (Max. insufflation pressure = pre-selected pressure (*) Note: Despite of pressure limitation, a sudden interruption of a current gas flow may result in pressure peaks which may exceed the pressure presetting.

REGULAR MODE : (i.e high flow insulation). The system allows the user to set the flow from 0 to 25 LPM ,Once the desired flow is set the insufflation recognizes the actual conditions during the select automatically the ideal flow performance (i.e from 0 LPM to actual set flow)

- Do not use the insufflator for hysteroscopic insufflation (distention of cavity in uterus) The use of this device is contraindicated whenever laparoscopy is contraindicated.

2. INITIAL OPERATION

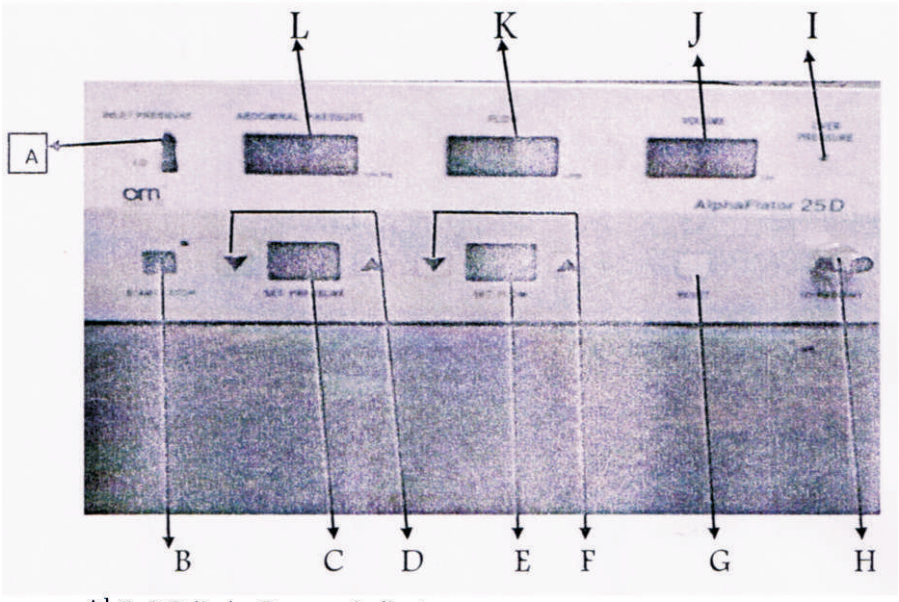
ARRIVAL CONTROL: Inspect the unit and accessories included for obvious damage or missing parts immediately after receiving them. Damage claims can only be acknowledged if the supplier will be informed immediately (within 24 hours).
Always use the original packaging if you have to return the unit or accessories.

SETTING UP THE UNIT:

Place the unit on a clean and even surface. Ambient temperature should be between 10°c & 40°c and relative humidity between 30% & 70%.

3. OPERATING THE DEVICE

3.1 FRONT PANEL



A] Co2 Cylinder Pressure indicator

B] Start / Stop

C] Digital Display for set Pressure (unit in mmHg)

D] Pressure pre-selection key (unit in mmHg)

E] Digital Display for set flow

F] Set flow keys (unit in Liter)

G] Reset Button (For Volume)

H] Patient Connector

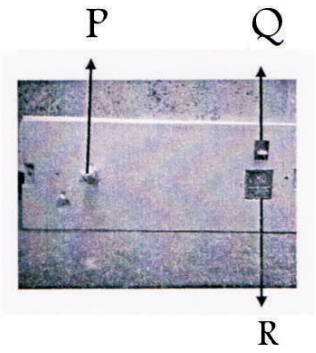
I] Over Pressure indicator

J] Gas Consumption indicator (Unit in Liter)

K] Actual Flow Digital indicator of Current gas flow (unit in LPM)

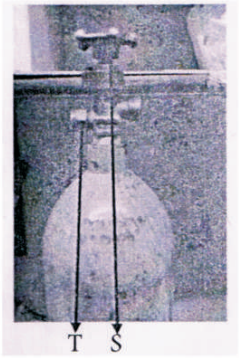
L] Actual Abdominal Pressure (unit in mmHg)

3.2 REAR PANEL



P] Connecting Hose pipe
Q] ON-OFF Switch
R] Connection to Main Supply

➢ Hose pipe And Co2 Cylinder

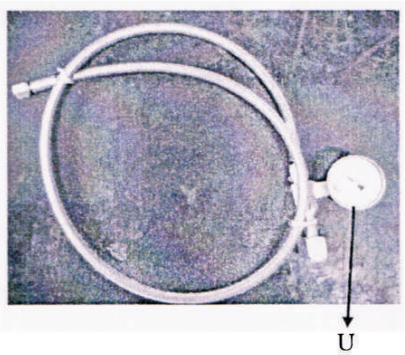


Co2 Cylinder

S] Co2 Gas Open & Closed

T] Hose Pipe Connetion

Hose pipe



U] Pressure Gauge

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4. FUNCTIONAL TEST

Control Unit : The function check helps to ensure that the unit is ready for use. This should be performed prior to any clinical use. Connect unit to power supply and switch on power switch

1. Power switch lights up in red in the rear panel.
2. Display and LED test is conducted.
3. "No gas" is displayed and in (A) low red LED glows.
4. Display (J) shows gas, (K) shows no, (L) shows 000.
5. Display (E) shows the default flow 3LPM and display (C) shows the default pressure 14mmHg.
6. Open the cylinder bottle valve regulator and (A) shows ok in green and display (J.K.L) shows 000.

Check the connected hose and regulator connection to ensure it is secure and not leaking (no hissing sound should be heard).

Start the insufflation in default mode (i.e. 14mmHg set pressure and set flow-3 LPM) the units starts to deliver a rapidly increase or decrease of flow/pressure using the keys as indicated in F and H.

➢ Veress-Needle

Connect the insufflation Veress needle to the insufflator by using an insufflation hose and start insufflation in LPM- Mode.
An undamaged Veress needle should allow a gas flow of approx. 1,5l/min run at a preset pressure of 14mmHg. If mechanical damage or narrowing should occur, e.g. due to sterile deposits/sediments the resulting flow rate will not reach its expected value.

Do not `use the unit if possible contamination is suspected, faults or malfunction are present or suspected, or the unit is obviously damaged.

The unit have to be repaired by authorized service personnel.

5. USE/HINTS

PROCEDURE

Endoscopic procedures, including the use of insufflators, are well documented in the relevant literature. The following notes should only be used as a general information and as a reminder of some of these procedures.

- Before each endoscopic procedure, flush the system with the insufflation gas, in order to remove any air which has penetrated the insufflation system.
- Start the operation, if possible, only with a full Co2 bottle. Always have a filled bottle of Co2 ready for replacement. Co2 is liquid in the bottle at a pressure of 60 bars and approx. 20°c. As long as a liquefied portion of Co2 remains in the tank, the pressure does not change. Due to these circumstances the amount of gas in the bottle cannot be determined based only on information concerning the pressure in the tank.
- Always start the primary insufflation in default mode. Hazardous insufflation, in the event of an incorrect positioning of pneumoperitoneal cannula, can be avoided when the desired pressure inside the body cavity is preset below the venous blood pressure.

Prior to the insufflation START make sure that the position of the Veress Neddle is correct and has been inserted properly.

- Always try to determine why there may be a high gas flow during the operation. A leakage somewhere along the insufflation path (e.g. tubing connection opened) may cause increased risk to the patient.
- To avoid reflux (fluids, e.g. rinsing solution…) Into the device & the insufflation path please make sure that the insufflator was installed always above patient level.
- Remove the insufflation hose from the insufflator before switching OFF the unit.
- Co2 evaporates rapidly from the insufflation system.
- If the adapted insufflation line is not open, the resulting negative pressure may cause severe damage to the Electronic system.

6. SAFETY FUNCTION

A) Safety Function
The insufflator is equipped with an alarm signal to indicate any dangerously high or low abdominal pressure as it may be caused e.g. By an unfilled or incorrectly connected gas cylinder. The equipment is fitted with safety release valve to avoid over pressure.

B) Pressure exceeding above set limit
The abdominal pressure exceeds acoustic signal will be heard as well as a visual signal. The signal will end only after the pressure falls below the set limit.

C) Automatically Control of Exceeding Pressure
In case of more than 35mmHg of the preselected pressure is reached again.

D) Stand By Mode
When the insufflator is in standby (start LED not glowing) the pressure from the abdominal side will default automatically by venting the gas in the atmosphere flow indicator A will display ' OFF'.

➢ MONITORING OF THE Co2 BOTTLE
When the filling pressure of the connected Co2 tanks drops / below a pressure of 5 bar and optical warning is activated of the red LED in the bottle symbol on front panel. Also monitor the high pressure regulator.

➢ CONCLUSION TEST
Monitors the insufflation line. In the event there is no gas flow during a period of 15 sec, despite active insufflation, the unit checks whether the insufflation line is concluded or the body cavity was just filled up according to the pre- setting.

7. CARE/MAINTENANCE/ SERVICE

➢ CARE

In addition to proper operation and servicing, effective protection of the unit against damage includes setting up to the unit safely. This means safe setting up the unit on its supporting surface but also includes protecting the unit from moisture, dirt, and contact with flammable or explosive materials. To ensure that the heat generated during use is abducted properly, avoid covering the ventilation.

➢ CLEANING

- Unplug the unit before cleaning.
- Unit may be cleaned only after cooling down.
- Avoid fluids entering into device!

➢ The exterior surface may be treated with a cleaning detergent that does not damage the paint.

➢ Please observe the accordance to national regulations.

➢ Avoid using flammable or explosive detergents.

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- In case of using special detergents make sure that the liquids has completely evaporated and avoid fluids entering into the device before the unit is switched on again.
- For cleaning purposes please use only clean, soft and fluff-free cloth.

8. INSPECTION

The unit must be inspected by an authorized OM SURGICALS service technician at least once a year. In accordance with the special safety regulations for medical appliances, all service work, such as annual inspection, repair, alterations, calibration, etc. May only be performed by the manufacturer or authorized persons of the company. In case of unauthorized opening, repairs or alternation OM SURGICALS is not liable for the safety and proper functions of the device.
If necessary OM SURGICALS will provide further technical information only for authorized and trained personal if required.

- Repairing & returning the unit

If a repair is required, please inform OM SURGICALS or your authorized agent. Pack the cleaned (uncontaminated) unit (Use only the original packaging) and return it to OM SURGICALS. Describe the fault or the malfunction and indicate the person we may contact for further questions.

- Responsibility

Unit and accessories are approved before leaving the production. Liability for function, performance and safety according the legal regulations only when the unit is maintained by authorized and trained persons and when the unit is only used for the intended use. Service authorization by OM SURGICALS only.

9. STANDARD LIST

Description	Qty
Alphaflator 25D Co2 Insufflator	1
Luer Lock	1
Silicon tube reusable	1
Pressure regulator with high pressure tube	1
Spanner set	1
Mains Cord	1
Manual / Technical description	1

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10. TECHNICAL DATA

- Voltage range : 100 – 240 Vac
- Frequency : 50 Hz
- Power Consumption : 60VA
- Miniature Fuse : 3 Amp
- Operating environment : 10° - 40°C ambient temperature
  30% -70% relative humidity
- Storage & transportation environment : -40° to +70°C ambient temp
  10% - 90% relative humidity
- Selectable Pressure : 1- 30mmHg in step of 1mmHg
- Abdominal Pressure : ±0.5 mmHg
- Gas Flow : ±0.5 I/min
- Volume : ±5% display tolerance
- Insufflation Medium : Co2 medical grade
- Max gas flow : 25 I/min (open condition)
- Min gas supply pressure : 5 kg/cm2
- Max gas supply pressure : 80 bar (1200 psi)

11. TROUBLE SHOOTING

TROUBLE SHOOTING Co2 25D INSUFFLATOR			
Sr. No	Description	Possibility	Remedy
1.	No indication on regulator	Gas cylinder empty	Replace with new cylinder
2.	High pressure O.K. but low pressure not indicating	Regulator failure or gauge malfunction	Change the regulator
3.	Low pressure O.K. but high pressure not indicating	Regulator failure or gauge malfunction	Change the regulator
4.	Condensation of the Co2 gas (regulator becoming cold)	Not tightened properly with cylinder also heater is OFF	Connect firmly with cylinder and ON the heater also
5.	No flow from the system		To replace the valve call authorized person.

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➢ TECHNICAL SERVICE

Unit including accessories should be serviced every year by:

OM SURGICALS
Unit No.65,Unique industries Estate,
Dr. R. P. Road, Opp.Jawahar Talkies,
Mulund (W), Mumbai-400 080.
OFF : +91-22-2567 0626

Technical head : Devendra

Engineer: Vishal

Other service addresses can be obtained from the address indicated above.

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Date of Installation	Installed By
Model No.	Serial No.
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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OUR OTHER PRODUCTS RANGE

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"Happy Home", 2nd Floor, 23, Karanpara,
B/h. S.T. Bus Stand, Kanak Road,
Rajkot-360 001. Ph. : 0281-2232871/2243159
Mo. : 98250 69069 - 98250 45997
Email : westernsurgical@gmail.com
Email : info@westernsurgical.in

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