Ackermann©

USER MANUAL 16-2045
FUSION INSUFFLATOR

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Contents

1 Preface

Thank you for the confidence you have demonstrated by purchasing the Ackermann Fusion Insufflator.

In order to make the best use of this Fusion device while having all the necessary precautions at your disposal, it is essential for you to become acquainted with this manual.

 Symbol correspond to points requiring special attention.

 Symbol provides advice.

To facilitate installation and use of the device, we have attempted to make the device manual more practical. Consequently, references to the product presentation on page 35 (like D1 for example) will be provided for easier viewing of the relevant product parts.

This user manual is an integral part of the device. It must be made available to the user.
For the proper use and correct handling of the device, please follow the instructions herein.
The user alone shall be responsible for any damage that may result from improper use.

2 About the device

The Ackermann Fusion insufflator is used for performing surgical or diagnostic endoscopic procedures. It is designed for the purpose of creating and maintaining the pneumoperitoneum (distension of the abdominal cavity with CO2) as part of these procedures. The insufflator transfers medical grade CO2 through a tubing hose, into the abdominal cavity, so as to create and maintain a pneumoperitoneum it under a defined pressure.
It is equipped with a gas outlet and an external desufflation valve for protecting the internal circuits.
Its ease of use, capacity for high flow rates and automatic flow rate regulation based on a pressure setpoint makes it the ideal medical tool for multidisciplinary use.

This insufflator includes:
· A power cord;
· A user manual;
· A Quickstart guide;
· An external filter;
· An open-end spanner for the high-pressure tubing hose connector, and for connecting/disconnecting
the external filter.

Optional accessories:
· Reusable Y-tubing 16-2040-100Y;
· Disposable viral filter 16-2040-200;
· High-pressure and low-pressure tubing hoses for connection to CO2 cylinders and CO2 wall points:

Ackermann Art. Nr.:
· 16-2040-2000 High pressure hose with US bottle connection
· 16-2040-2000 High pressure hose with DIN bottle connection
· 16-2040-2000 High pressure hose with PIN index connection

We recommend checking the condition of the external filter and replacing it every 6 months if necessary.

⚠ For the United States and Canada, use a “hospital grade” power cord. This must be connected to a “hospital grade” mains socket.

⚠ This equipment has been delivered to you in packaging which is to be retained for use if transporting the device.

⚠ United States federal law restricts the sale of this product to medical doctors or under their advice.

C1	External desufflation valve
C2	CO2 outlet – connector for tubings
C3	Main power socket
C4	Service – to be used by manufacturer only
C5	Connection to Ackermann Fusion devices
C6	CO2 input – medical grade CO2 bottle or wall plug
C7	Equipotenional plug
L1	Touch screen – 7“ (± 0.1)
S1	Standby button
S2	Power button
I	Label

3 Safety instructions

⚠ Read the user manual.

⚠ This user manual is an integral part of the device. It must be made available to the user.

For the proper use and correct handling of this device, pleas follow these instructions.
The user alone shall be responsible for any damage that may result from improper use.

• Comply with the conditions of use and storage

• The device must be opened only by a competent technician authorized by the manufacturer

• Do not insert metal objects into this device. This is to avoid any risk of electrical shock, fire, short-circuit or hazardous emissions

• Do not expose the device to splashed water or store in damp areas

• Only use the accessories supplied with the device or recommended as options by the manufacturer

• Do not place heavy objects on top of the device;

• This device is not sterile

• If the power cord is damaged, switch off the device immediately. It is dangerous to operate this device with a damaged cord

• To unplug the cable, pull it by the plug, never pull on the cable itself

• Unplug the device from the main power if you do not intend to use it for several days or more

• Use only the disinfectant methods recommended in section 8

• Prior to each use, make sure that the device does not have any rough surfaces, sharp edges or protruding parts that could cause safety problems

• To avoid any risk of electrical shock, this device must be connected only to a power system equipped with protective grounding

• Any modification of this device without authorisation of the manufacturer is prohibited. If the medical device is modified, an inspection and a test must be carried out to ensure that the medical device complies with the safety regulations

• This device is to be used on individuals (patients) fit to undergo an endoscopic procedure

• The use of tubing hoses or accessories other than those specified may lead to malfunction of the device and incorrect measurement of the instantaneous pressure

• The insufflator is intended for professional use in operating theatres

• To ensure proper hygiene between patients and avoid contamination, make sure tubes are thoroughly sterilized

• Do not drop the device. If the device falls, do not reconnect the device but send it back to your authorised distributor

• Do not move the device when an operation is in progress

• The use of accessories, transducers or cables other than those specified, with the exception of transducers and cables provided by the manufacturer of the insufflator, can result in increased emissions or reduced insufflator immunity

No additional multiple-socket outlets or extension cords must be connected to the EM system.

⚠ It is advisable to have a second insufflator in the operating theatre so that action can be taken if the device fails to perform or if a deterioration in performance is noticed.

⚠ The use of this device is always contraindicated in cases of intra-abdominal distension, or when laparoscopy is contraindicated. Kindly refer to the laparoscope user manual for absolute and relativec ontraindications.

⚠ This instrument is contraindicated for hysteroscopic insufflation; it should NEVER be used in cases of intrauterine distension.

Note: the insufflator distension pressure for laparoscopy must never exceed 25 mm Hg.

WARNINGS

• **Metabolic acidosis and resulting cardiac irregularity**
Avoid prolonged intra-abdominal pressures above 20 mm of mercury.

• Reduction of respiration with compromised diaphragmatic movement
• Reduction of venous return
• Reduction of cardiac output
• Acidosis

Excessive absorption of CO2 is due to either a too high flow rate or excessive pressure, or both. The abdomen can be sufficiently distended by a pressure between 10 and 15 mm of mercury. It is rarely necessary to select an abdominal pressure higher than 15 mm of mercury. At these levels, the extent of intravascular penetration should be low. Pressures higher than 20 mm of mercury are hardly ever necessary; they will increase the quantity and the speed of intravascular penetration. Adequate respiration helps to prevent problems associated with CO2.

• **Idiosyncratic reactions**
For patients suffering from microdrepanocytic diseases or pulmonary insufficiency, the use of these devices
can present an increased risk of metabolic imbalance related to the excessive absorption of CO2.

• **Hypothermia**
High-flow insufflation allows for a potential risk of hypothermia; therefore we recommend using a heating
system to keep the patient's temperature stable.

• **Gas flow**
Surgical procedures must be carried out with insufflators able to reach flows between 4 to 10 l/min. Insufflators providing lower flow must only be used for diagnostics procedures.

• **Gas coagulation system**
Some medical devices delivering gas to the interior of the peritoneal cavity during surgical laparoscopies (gas lasers, for example) may lead to abdominal over-pressurization. If venous sinuses are formed, triggering an embolism, the use of a secondary gas source that is far less soluble in the blood than CO2 can cause a rapid rise in intra-abdominal pressure. We recommend avoiding the use of these coagulation systems during laparoscopic procedures, as we, the manufacturer could not be held responsible for any incident associated with their use.

• **Bacterial filter**
The use of a hydrophobic bacterial filter is essential for preventing cross-contamination with the patient

The potential equalisation plug located at the back of the Fusion unit can be used to equalize the grounding potential of the medical device with that of all the devices plugged into the main power in the environment. Use the shared grounding system in the hospital or the building.

Connect the potential equalisation cable to the equipotential socket C7 at the back of the device.

⚠ Devices connecting to the input/output ports must comply with the IEC 60950-1 standard.

4 Regulatory advice

4.1 Compliance

This device is designed and manufactured by a Ackermann proven to have a certified quality system.
It meets the requirements of European directive 93/42/CEE, on medical devices.
Consequently, it particularly meets the standards of electrical safety (IEC) and electromagnetic compatibility (EMC) ad hoc.

4.2 Electromagnetic interferences and electrostatic discharge

Although this product complies with EMC standards, it may in very special circumstances interfere with other devices, or itself be the object of interference from other devices or an unfavorable electromagnetic environment.

In order to avoid these situations, it is advisable to:
• Ensure of the quality of the electric power system (especially the grounding of all devices and medical carts.
• Keep the device away from electromagnetic sources (e.g. compressors, motors, transformers, HF generators, etc.).

4.3 Medical device vigilance

Like any medical device, this device is subject to the stipulations governing medical device vigilance, and therefore any serious malfunction must be reported to the manufacturer as quickly and as accurately as possible. For manufacturer contact details, refer to the first page of the manual.

4.4 End of lifecycle

This device carries the recycling symbol in compliance with European directive 2002/96 CEE on Waste Electrical and Electronic Equipment (DEEE or WEEE). By correctly disposing of this device you are helping to prevent harmful effects on the environment and on human health.

The  symbol displayed on the device and on the accompanying documentation indicates that this product cannot under any circumstances be treated as household waste. It must therefore be delivered to a waste collection center for the recycling of electrical and electronic equipment. In disposing of it, please comply with the waste elimination norms in effect in the country where it is installed.
For further details on the treatment, recovery and recycling of this device, kindly contact your nearest distributor who will advise you on the procedure to follow.

5 Installing the device

This medical device is intended for use by a qualified surgeon for endoscopic applications. No special training is required to install the device. Kindly refer to the instructions in this manual.

5.1 Installation

- Place the device on a stable surface and have on hand the various accessories required for it to function;
- Make sure the area is well ventilated.

Connect the power cord to the mains socket of the device [C3]; Check that the external filter is properly in place on the CO2 input socket [C6]. This is necessary for the protection of the internal circuits and will help prolong the life of the insufflator.

5.2 Connecting to a cylinder of medical CO^2

⚠ Maximum allowed operating pressure (60 bars)

⚠ Never begin any surgical operation without having a CO2 replacement cylinder. Only use medical-grade CO2, in compliance with European standards.

⚠ Place the CO2 cylinder in a vertical position, so that it is secure with the upper part facing upwards, if possible on the same medical cart as the insufflator.

⚠ Never use the insufflator connected to a cylinder in a horizontal position or with the upper part facing downwards.

⚠ Use the supplied open-end spanner to tighten the connector attached to the cylinder outlet, and the connector attached to the external filter on the input port on the insufflator [C6].

5.3 Connecting to a medical CO^2 central wall point

Manually connect the low-pressure hose to the wall connector .

⚠ Minimum allowed operating pressure: 3 bars.

⚠ Only use with the CO2 gas central wall system, in compliance with European standards.

5.4 Disconnecting the CO^2 cylinder

⚠ Before unscrewing the high-pressure hose:
- Check that the valve on the cylinder is closed, then:
• Lower the pressure inside the system by slowly unscrewing the tubing hose.
OR
• Use the Purge function (on the interface, tap PURGE) after closing the valve on the bottle.

5.5 Disconnecting from the wall point

Manually disconnect the low-pressure hose from the wall point.

5.6 Connecting to the Ackermann Fusion Camera

Turn off the devices.
Connect the cable supplied with the camera to the socket on the back side of the camera control unit, and then to the back side of the insufflator [C5].
Turn on the devices.

6 Operating guidelines

This insufflator in only intended for use in diagnostic procedures or laparoscopic operations. Any use outside of these areas constitutes improper use of the product and the user will therefore be considered responsible for such use. The manufacturer does not accept any liability in this case. This device must only be used by qualified staff. The surgeon and anaesthesiologist shall at all times be responsible for the device and the anaesthesiologist shall undertake special vigilance of gas levels in the blood. The safety features on this device are in no way intended to reduce the responsibility of medical staff with respect to constant attention to the screen and continuous monitoring of the patient.

6.1 Activation

Turn the switch [S2] to position “1”; the device is now in standby mode (the indicator light on the Standby button [S1] will be flashing, and the Ackermann logo should appear on the touch screen [L1]);
Press the Standby button [S1] or tap the touch screen to start the device (the indicator light comes on and the calibration phase, which lasts for a few seconds, starts). Pressing the Standby button again puts the device back in standby mode.
Note: If the insufflator is connected to the Ackermann Fusion camera, activating the camera will automatically activate the insufflator and vice-versa. However, the insufflator can be put in standby mode, or turned on, independently.

6.2 Fitting the tubing hose

⚠ The manufacturer cannot be deemed responsible for reactions or malfunctions associated with the use of damaged or inappropriate tubing hoses.

⚠ Do not use the tubing hose if its packaging is damaged.

⚠ Sterile tubing hoses are disposable; do not re-sterilise them.

⚠ The use of a hydrophobic bacterial filter is essential for preventing cross-contamination between patients. It must be replaced for each patient. Open the first pack of film wrapping on the tubing hoses. Hand the second one to the staff In a sterile environment.

⚠ Keep the sterilised tubing hose for the patient in the operating theatre.
Connect the insufflation part of the tubing hose to the gas outlet on the insufflator [C2] and the external desufflation part of the tubing hose to the connector [C1] provided for this purpose.

⚠ The tubing hose must be free when inserted, without any knots, and must not be obstructed.
Connect the (sterile) distal end to the patient.

⚠ We recommend connecting the patient-end of the tubing hose to a Verres needle in the first phase. This first phase corresponds to low-flow insufflation (max. 2L/min) until the pressure setpoint is reached. Once the pressure setpoint has been reached, you can move on to the second phase consisting of high-flow mode (up to 45L/min) with the patient-end tubing hose connected to the trocar.

⚠ The use of a verres needle is not recommended for high-flow mode.

6.3 Adjusting the pressure setpoint

⚠ This operation must be carried out by a surgeon or under the supervision of a surgeon.
This insufflator is equipped with automatic flow rate regulation to attain and maintain a pressure setpoint, and therefore the pneumoperitoneum
Use the “ + ” and “ - ” buttons to select the pressure desired in the abdominal cavity.

The pressure generally used is 12 mm Hg.

As a precautionary measure, you will be asked to confirm the pressure if you wish to exceed the 15 mm Hg threshold.

The pressure can be adjusted to a maximum of 20 mm Hg in Standard mode, and to 25 mm Hg in bariatric mode.

The automatic change-over must be selected on the surgeon’ s orders.
Press the “STOP” button to halt insufflation.

6.4 Activating / Switching-off insufflation

Press the “RUN” button on the interface menu to start insufflation. A chronometer is displayed on the screen when insufflation is in progress. The MENU is not accessible when insufflation is in progress. To access it, insufflation must be halted by tapping on “STOP”.
Insufflation begins in low-flow mode (2 l/min), so that the pneumoperitoneum is created in the safest of conditions. When the low flow rate is activated, the “low flow rate” is displayed in blue on the screen.
The high flow rate mode is activated manually by tapping the corresponding sign on the interface menu or automatically if automatic change-over is activated (in the menu parameters).
Automatic change-over is used to automatically change from low-flow mode to high-flow mode once the pressure setpoint has been reached. When the high flow rate is activated, “high flow rate” is displayed in blue.

⚠ The automatic change-over must be selected on the surgeon’s orders. Tap on “STOP” to stop the insufflation.

6.5 Controls

When the pneumoperitoneum has been created at the required pressure, the insufflator will keep this cavity at the pressure selected and will immediately compensate for any leakage of CO2.

⚠ The high-flow mode must be activated in order to benefit from maximum reactivity from the insufflator.

⚠ When the determined pressure has been reached, the insufflator will stop insufflating. The insufflator will resume as soon as the pressure in the cavity falls below the pressure selected.

⚠ Control the pressure in the trocar during gas input.

6.6 Excessive pressure

As soon as the instantaneous pressure in the cavity exceeds the pressure setpoint by 2 mm Hg:
- The message “EXCESSIVE PRESSURE” is displayed on the screen.

The insufflator then opens the external desufflation valve to lower the pressure in the cavity.
As soon as the pressure in the cavity exceeds the pressure setpoint by 5 mm Hg:
- The instantaneous pressure display turns orange

The insufflator then opens the external desufflation valve to lower the pressure in the cavity.

6.7 Parameters

The instantaneous flow is shown on the screen in litres/minute.
The volume of gas used is shown in litres on the screen (accurate to the decilitre. For illustrative purposes only.)
This measurement begins at the same time as insufflation and is only reset to zero when it reinitializes each time the device is started up (or from the parameters interface menu).
If necessary, set it to zero using the menu.

⚠ Only use medical-grade CO2, in accordance with European standards.

6.8 End of operation

Halt insufflation by tapping the “STOP” button. The chronometer stops.
Immediately disconnect the tubing hoses between the trocar and the insufflator to avoid any liquid or gas backflow into the device.
The tubing hoses used must be discarded after use in an appropriate container.
The total volume of gas insufflated during the operation is displayed; reset the gas counter to zero if another operation is planned without turning off the device.
Press the Standby button [S1] to put the device in Standby mode. Turn the power switch [S2] to the “O” position to turn off the device.

7 Special features

7.1 Control from the Ackermann Fusion camera head (Ackermann Fusion camera only)

The following insufflator functions can be controlled using one of the three programmable buttons located on the camera head: RUN (in low flow mode), HIGH FLOW RATE, STOP. A special communication cable must connect the Ackermann Fusion camera to this insufflator at the dedicated socket [C5] (see Ackermann Fusion camera user manual for further information on configuring this switch). In addition, this communication cable is for receiving feedback information (instantaneous pressure in the cavity, warning messages) on the surgical monitor.

7.2 Autonomous operation with the CO^2 cylinder

This patented function indicates the insufflation time remaining based on the remaining CO2 capacity in the cylinder. It helps the surgical team to better manage:
- surgical operation time,
- cylinder changes.

The autonomous function is triggered when the pressure of the CO2 cylinder is below 33 bars and when autonomy is equal to or less than 99 minutes.

7.3 Safety

• Preheating system

This warms the gas in the device.

• Automatic test

Automatic calibration of the device and testing of the basic components on each start-up, in less than one second.

• Detection of tubing hoses

The device will only start if a tubing hose is connected both to the CO2 outlet and the external desufflation valve (for safety reasons, it is impossible to connect only one of these elements).

• Automatic flow rate adjustment

This insufflator automatically regulates the flow rate based on the operating conditions in order to maintain an abdominal pressure equal to the determined pressure.

• An additional pressure sensor

If the measurement circuit is not functioning properly, the consistency of the measurements is constantly monitored; this means that the insufflation cycles can be interrupted if there is the slightest doubt.

• High-pressure discharge valve

If excessive pressure is created in the high-pressure regulator, a safety valve is available to limit the risks.

• Bacterial filter

This filter limits the risk of cross-contamination between patients.

7.4 Low flow rate

In this mode, the insufflation flow rate is limited to 2 l/min to create the pneumoperitoneum. This flow rate is not sufficient to regulate the pressure inside the cavity in the event of substantial escape of gas and it will therefore be necessary to change to the high flow rate. By default, the insufflator starts in low flow mode. The surgeon can choose between manual and automatic mode to activate the high flow rate.

7.5 High flow rate

When the pneumoperitoneum is created, activating this mode enables a maximum flow rate of up to 45 L/min to be reached. This capacity is then used to compensate for all types of leakage. It is advisable not to use verres needles in this mode.

7.6 Automatic High/Low flow rate

If the automatic change-over switch is set to “ON” in the settings, the device begins to insufflate in low-flow mode, and then changes to high-flow mode once the pressure setpoint has been established in the cavity.

7.7 External desufflation valve [C1]

Our insufflators are equipped with a valve for releasing excess CO2 pressure from the device so as to avoid:

- Excessive pressure in the pneumoperitoneum
- Any backflow of fluid inside the device, and in this way avoid any risk of deterioration or contamination.

7.8 Testing of medical CO^2 cylinder pressure

This latest generation of insufflators is equipped with a pressure measurement system in the cylinder with continuous visibility.
When the pressure in the CO2 cylinder reaches 40 bars, the corresponding logo is displayed in orange. When the pressure in the CO2 cylinder reaches 20 bars, the corresponding value is displayed in orange.
Below a pressure of 10 bars, the insufflator cannot start. The display of the input pressure value changes to orange.

7.9 Testing of medical CO^2 central wall point

This latest generation of insufflators is equipped with a CO2 gas central wall point pressure measurement system with continuous visibility. Below a pressure of 2.8 bars, the insufflator cannot start. The display of the flow rate input value changes to orange.
From 10 bars, the insufflators will change automatically to “cylinder” mode. Only to be used with a medical CO2 gas central wall point, in compliance with European standards.

7.10 Touch screen [L1]

For better communication and for easier use, we have equipped our latest generation of insufflators with a user-friendly touch screen. This serves to provide the following information:

• warnings and error messages
• indications that the cylinder is empty
• indications of the instantaneous pressure in mm Hg
• indications of the pressure setpoint in mm Hg
• indications of the flow rate in l/min
• indications of the volume of CO2 used in litres
• status indications: on / off and “high flow rate” / “low flow rate”
• indications of the operating mode

7.11 CO^2 central wall point and CO^2 cylinder capacity on the same device

This device can be connected to the CO2 system between 3 and up to 5 bars and to medical CO2 cylinders. In the MENU, simply select “WALL POINT” or “CYLINDER”.

7.12 Pure function

If a CO2 cylinder is connected, the interface “Purge” button can be used to purge the high-pressure hose before disconnecting it from the cylinder. To do so, remove the tubing hose from the insufflator, close off the CO2 cylinder and press the “Purge” button.

7.13 Hose obstruction messages

A message is displayed on the screen when the insufflator detects a tubing hose obstruction.

7.14 Operating modes

This insufflator cannot work in two modes with differing maximum value settings for the pressure setpoint.
The standard mode allows a maximum pressure setpoint value of 20 mm Hg. The bariatric mode allows a maximum pressure setpoint value of 25 mm Hg.

8 Suggested decontamination procedures

⚠ The insufflator is a medical device, not heat resistant and it cannot withstand immersion; consequently it should be disinfected with a non-woven medium saturated disinfectant detergent.

⚠ Decontamination methods and/or selected tools, it remains under the full responsibility of the staff concerned.

⚠ This device cannot be autoclaved.

⚠ Existing alkaline solutions for the disinfection of certain medical devices are NOT RECOMMENDED for the disinfection of this device.

⚠ Always disconnect the device before cleaning it.

After each use:

- Discard disposable sterilized tubing hoses; do not attempt to re-sterilse them.
- Clean up all possible spatters on the insufflator by removing them with a slightly moistened cloth.

⚠ The device must always be decontaminated before sending it back to the manufacturer or distributor.

9 After-sales service and maintenance

No particular maintenance operation is needed for this device.

⚠ Note: misuse is not covered by the warranty. If a fault persists and the device has to be returned to the distributor, ensure that it is shipped in its original packaging.
Similarly, it is advisable to return the device in its entirely (control unit and power cables). Kindly attach to the shipping order a short explanatory note about the fault detected.

⚠ The equipment must be disinfected before returning for repair. When returning the equipment, check its condition and make notes on the delivery note if necessary, confirming them with the carrier by registered letter as soon as possible.

⚠ Please contact your distributor who will guide you through the return process.

10 Troubleshooting

Warning	Possible Cause	Measures to take
Orange cylinder logo	Cylinder pressure at 40 bars	Change the cylinder. it is advisable to prepare a replacement cylinder as soon as the cylinder pressure reaches 40 bars.
	gas cylinder valve closed	Open the valve
	high-pressure hose connector on the insufflator disconnected	Turn off the device, check that the CO2 gas is flowing and turn the device back on
Excessive pressure	sporadic action on the pneumoperitoneum	none. - if the pressure exceeds the pressure set by 2 mm hg, the device will create mild exsufflation.
	Tubing hose tangled	stretch out the tubing hose
	Trocar valve closed during insufflation	Open the trocar
Chck the tubing hose	Tubing hose missing	Connect the tubing hose
	The tubing hose is not correctly connected	Correctly connect the tubing hose to [C1] and [C2]
	Tubing hose fault detected	Sent the device to the distributor for repair
Tubing hose obstructed	Bent tubing hose	stretch out the tubing hose
	Trocar valve closed during insufflation	Open trocar valve
CO2 not detected	gas cylinder valve closed	Open the valve
	high-pressure cylinder or insufflator hose disconnected	Correctly connect the hose to the insufflator and to the cylinder
	CO2 gas wall point system faulty	Check whether the pressure supplied by the CO2 gas wall point system is higher than 3 bars.
	insufflator hose connection / wall point system connection	Carefully connect the hose to the CO2 gas wall point outlet and to the insufflator

Note:
If the insufflator does not switch on, this could be due to damage to the fuses. If so, it is advisable to turn off the power, check and if necessary replace the fuses (use only T25AL – 250 V delayed-action UR fuses)
For any other problems, contact your nearest after-sales service department.

11 Technical characteristics

Pneumatics:
· CO2 gas supply system: US 7/16˝ connector
· Pressure range:
- CO2 cylinder: 10 to 60 bars
- central gas wall point outlet: 3 to 5 bars.
· Maximum flow rate
- 45 l/min in high-flow mode
- 2 l/min in low-flow mode
· Pressure setting: 0 to 25 mm Hg (accuracy: 1 mm Hg)
· External exsufflation valve
· Automatic low-flow / high-flow function selection option

Interface:
· Touch screen displaying: immediate flow rate, pressure in the cavity, total volume of CO2
used and low cylinder levels
Energy supply:
· Types of energy: 100 - 230 V AC 50 - 60 Hz
· Fused protection: 2 x 2.5 AT - 250 V delayed-action UR fuses
· Power consumption: 75 VA

Mechanics:
· Dimensions (W x H x D): 310 x 136 x 385 mm
· Weight: 8000g

Operation - transport and storage environment:
· Operating temperatures between + 10 °C and + 40 °C
· Operating relative humidity between 30 and 75 %
· Transport and storage temperatures between - 10 °C and + 45 °C
· Transport and storage relative humidity between 20 and 85 %
· Operating, transport and storage atmospheric pressure between 700 hPa and 1060 hPa

Standards:

· Electrical protection: class 1, type CF

· Compliant with standard IEC 60 601-1; with variants for the United States and Canada

· No protection against water (IPXO)

· Not suitable for use in the presence of a flammable anaesthetic mixture, air, oxygen or nitrous oxide

12 Electromagnetic compatibility

12-1 Manufacturer's guide and declaration – electromagnetic emissions		
This insufflator was designed to be used in the electromagnetic environment specified below. The user must ensure that it is in fact used in this environment.		
Emission test	Compliance	electromagnetic environment - guide
RF emissions CisPR 11	group 1	This insufflator only uses radio energy for its sub-systems. it therefore emits very weak RF energy and is not likely to interfere with nearby electronic devices.
RF emissions CisPR 11	Class A	This device must be used on premises other than domestic premises and premises directly connected to low-voltage public electric power systems providing power to buildings for domestic purposes.
Harmonic emissions en 61	Class A	
Variations in voltage/ flashing EN 61000-3-3	Compliant	

12-2 Manufacturer's guide and declaration – electromagnetic immunity

This insufflator was designed to be used in the electromagnetic environment specified below. The user must ensure that it is in fact used in this environment.

safety test	IEC 60601 level of gravity	Compliance level	electromagnetic environment - guide
electrostatic discharges EN 61000-4-2	± 6 kV via Contact ± 8 kV via air	± 6 kV ± 8 kV	The floor must be wooden, concrete or tiled. if the floor is covered with synthetic material, the relative humidity must be at least 30%.
Rapid transient peaks EN 61000-4-4	± 2 kV electric lines ± 1 kV input/output lines	± 2 kV ± 1 kV	The quality of the electric power supply must be that of a commercial or typical hospital environment.
electric shocks EN 61000-4-5	Differential mode ± 1 kV shared mode ± 2 kV	± 1 kV ± 2 kV	The quality of the electric power supply must be that of a commercial or typical hospital environment.
Power failures, short power interruptions and variations in voltage EN61000-4-11	• <5% UT – 10 ms • 40% UT – 100 ms • 70% UT – 500 ms • <5% UT – 5 s	<5% UT 10 ms <40% UT 100 ms <70% UT 500 ms <5% UT 5 s	The quality of the electric power supply must be that of a commercial or typical hospital environment. if the user of this insufflator must be able to continue working during power interruptions, it is advisable for this insufflator to be supplied with power from a UPs or battery.
system frequency magnetic field (50/60HZ) ieC61000-4-8	3 A/m	3 A/m	The system frequency magnetic field must be at a level that is characteristic of its (health information system) location (50 / 60 HZ) in a commercial or typical hospital environment.
Note: UT is the nominal value of the electrical voltage applied during the test.			

12-3 Manufacturer's guide and declaration – electromagnetic safety

This insufflator was designed to be used in the electromagnetic environment specified below. The user must ensure that it is in fact used in this environment.

Safety test	IEC 60601 level of gravity	Compliance level	electromagnetic environment - guide
RF conducted EN 61000-4-6 RF emitted EN 61000-4-3	3 Vrms 150 khz at 80 Mhz 3 V/m 80 Mhz at 2.5 ghz	3V 3V/m	Portable and mobile RF communication devices – cables included - must not be used at a distance nearer than what is recommended. This distance is calculated by applying the formula corresponding to the transmitter frequency. Recommended separation distance d = 1,16 √P d = 1,16 √P 80 Mhz to 800 Mhz d = 2,33 √P 800 Mhz to 2.5 ghz Where P is the maximum output power from the transmitter, in Watts (W), assigned by the manufacturer of the transmitter and (d) is the recommended separation distance in metres (m). The field strengths emitted by fixed RF transmitters – which must be established by in situ electromagnetic measurements – must be lower than the compliance strength in each frequency band. interference may be caused by devices on which the following symbol is displayed  :

Note 1: at 80 Mhz and 800 Mhz, it is advisable to use the highest frequency band.
Note 2: these recommendation may not be applicable in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.

a The field strength of fixed transmitters, like base stations for radio telephones (mobile and fixed line) and mobile land radio systems, amateur radio systems, AM/FM radio communication systems and TV systems cannot in theory be evaluated with accuracy. To analyse the electromagnetic environment due to fixed RF transmitters, on site measurements must be taken. If a field strength measured in the environment in which this insufflator is used exceeds the applicable compliance levels shown above, check whether this insufflator is functioning accordingly. If it is observed to be functioning abnormally, additional measures will have to be taken, such as a change of direction or repositioning of the referencing system.
b Outside of the 150 khz to 80 Mhz frequency band, the field strength must be lower than 3 V/m.

12.4 Recommended distances between portable and mobile RF communication systems and this insufflator

This insufflator is designed to be used in an electromagnetic environment in which the RF interference produced is controlled. The user of this insufflator can help avoid electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication systems (transmitters) and this insufflator, as recommended below, based on the maximum output strength of the communication system.

Assigned maximum output strength of the transmitter in W	separation distance depending on the frequency dd of the transmitter m		
	150 khz to 80 Mhz	80 Mhz to 800 Mhz	800 Mhz to 2.5 ghz
	$d = 1{,}16 \sqrt{P}$	$d = 1{,}16 \sqrt{P}$	$d = 2{,}33 \sqrt{P}$
0.01 0.1 1 10 100	0.116 0.366 1.16 3.66 11.6	0.116 0.366 1.16 3.66 11.6	0.233 0.736 2.33 7.36 23.3

Note 1: at 80 Mhz and 800 Mhz, it is advisable to use the highest band frequency.
Note 2: These recommendation may not be applicable in all situations. The propagation of electromagnetic waves is modified by absorption and reflection due to structures, objects and people.

For transmitters for which the maximum output strength is not shown in the table above, the recommended separation distance d, in metres (m) can be established by using the equation applicable to the frequency of the transmitter, where P is the maximum output strength of the transmitter in Watts (W) assigned by the manufacturer of the transmitter.

13 Symbols

S	Button
L	Indicator light
C	Socket
I	Label
	Manufacture date
	Manufacturer
Class 1	Class I product
	Conforming to European directive 93/42/EEC
	An equipotential earth socket conductor other than a protective earth or a neutral conductor, allowing direct connection between the electrical equipment and the equalizing bar of the installation potential. Please consult standard IEC 60601-1 3rd edition.
	T Timed Fuses UL/CSA Device of CF type
	CF-type device
	Electronic and electrical equipment put on the market after 13/08/2005. This symbol indicates that this product must not be processed with household waste.
	Read the user manual.


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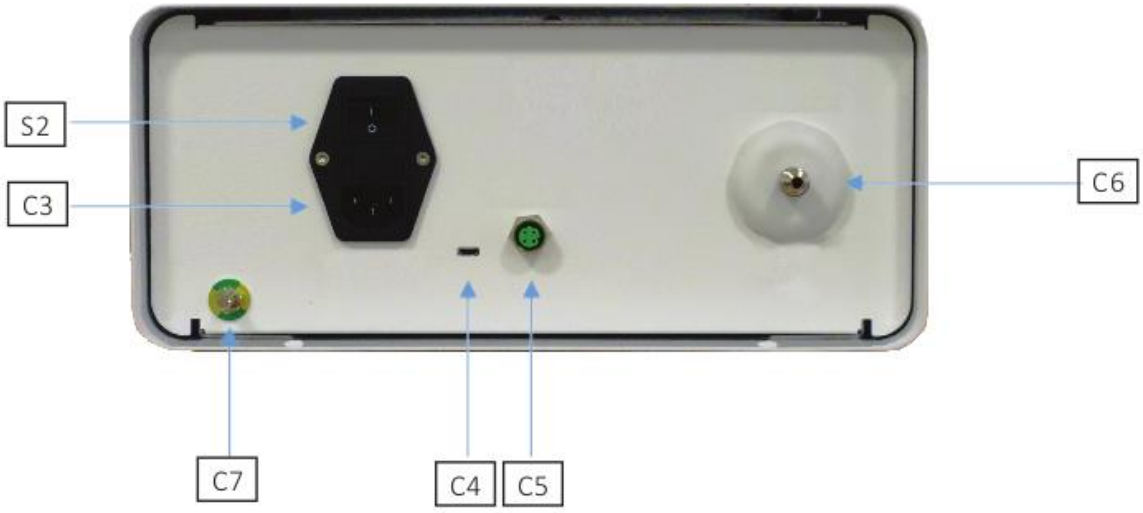
INSUFFLATOR
FUSION
12
48.2
86.4
5.2
14
Stop
C1
C2
L1
S1


S2
C3
C6
C7
C4
C5