

High-flow insufflation

P. NOVAK

Storz-Endoskop GmbH, Schaffhausen, Switzerland

Summary. Within the last decade, laparoscopy has developed from mainly a diagnostic technique to an extensive therapeutical procedure. This development has led, among others, to new or extended requirements for intra-abdominal insufflation. These requirements are outlined and analysed. A new generation insufflator, developed and manufactured by Karl Storz, is presented and evaluated. This instrument fulfills these requirements to a large extent by providing high-flow insufflation with up to 30 l/min average flow, further improved pressure control and optional gas heating to body temperature. Further, additional security functions are provided such as monitoring of the correct Veress needle placement, monitoring of the insufflation line status, active venting, good vision during smoke generation (CO₂ laser, electrocautery) by semi-continuous insufflation or display of selected functional parameters in the videoendoscopic image. Finally, an optional CO₂ gas humidification system is also provided.

Keywords: insufflation, CO₂ gas heating, CO₂ gas humidification, high flow, active venting, Storz Communication Bus

Introduction

Within the last decade, the laparoscopic operating technique has developed from being mainly diagnostic to an important surgical procedure. The main breakthrough was achieved by the introduction of the laparoscopic cholecystectomy. Today, many procedures such as myomectomy, laparoscopic hysterectomy, laparoscopic hernia repair, appendectomy etc., can now be performed laparoscopically. This development also afforded, besides novel instrumentation and operative techniques, a significant improvement of the laparoscopic insufflation.

The resulting requirements and the corresponding physical parameters and technical features are summarized in Table 1 and explained in more detail in the following section. The table shows no bilateral relationships among the items listed, because mostly multilateral relationships are present.

Basic requirements of abdominal gas insufflation

Optimal, stable abdomen distention

An intra-abdominal pressure of 10–15 mmHg proved to be

Correspondence: Dr Ing. Pavel Novak, Executive Director Development & Production, Storz-Endoskop GmbH, Schneckenackerstrasse 1, CH-8200 Schaffhausen, Switzerland.

an optimum with regard to sufficient abdomen distention and physiological acceptance. For maintaining this pressure during diagnostic laparoscopy, an insufflation flow at the range of 1 l/min is sufficient, because the CO₂ absorption by the intra-abdominal tissue is approximately only 300 ml/min [1]. Today, an insufflation flow capacity of at least 15–20 l/min has become mandatory for the surgical laparoscopy due to the following effects:

- an efficient aspiration of the irrigation fluid mainly by wall suction with gas aspiration capacity at the range of 10 l/min,
- an efficient smoke evacuation, which is necessary when using electrocautery for coagulation and/or cutting, or even mandatory when using CO₂ laser. In this case, an additional gas loss at the range of 10 l/min is common,
- in spite of or due to the more sophisticated instrumentation, the number of incisions and instrument changes during the treatment increases resulting in further significant gas loss,
- also, the techniques for removal of pathological tissue (myomas, uterus tissue, tumour tissue, etc.) mainly by morcellation or bags is accompanied with an extensive gas loss,
- finally, one has to consider the fact that an incidental loss of intraperitoneal pressure might endanger the patient's

Table 1. Basic requirements of abdominal gas insufflation

Medical requirements	Physical parameters	Technical features
Stable abdominal distention	High insufflation flow	High-flow capacity
Unobstructed vision	Stable intra-abdominal pressure	Continuous flow
Minimal invasiveness	Insufflation gas	Smart pressure control
Sterility	Gas temperature	Low insufflation pressure
Functional safety	Gas humidity	Active venting
Easy operation	Man-device interface	Fail-safes
No distraction		Gas heating
		Gas humidification
		Clear front panel
		Remote control
		Remote display

life, thus, a sufficient insufflation flow capacity is a significant safety feature.

Especially under the above-mentioned conditions the maintenance of a constant intra-abdominal pressure is becoming more sophisticated. Not only the avoidance of any pressure drop, in order to maintain unrestricted working conditions for the surgeon, but also the avoidance of overpressure for minimizing the influence to the cardiovascular system is extremely important. Also the strongly ranging size and compliance of the abdominal cavity (from children to adults) must be tolerated.

These requirements can only be fulfilled by a very smart insufflation control with an efficient venting as a means of avoiding an overpressure when additional external gas insufflating sources like CO₂ laser with gas cooling or argon beam coagulator (ABC) are used. Such an additional gas insufflation may otherwise easily lead to a dangerous intra-abdominal overpressure, when not vented efficiently [2].

Unobstructed vision

For achieving an unobstructed vision the following conditions must be maintained:

- stable abdomen distention,
- efficient smoke evacuation,
- efficient light source,
- efficient video equipment and/or endoscope optical system,
- clear endoscope tip.

The first two conditions were addressed above, the next two cannot be influenced by the insufflation system. As far as the endoscope tip is concerned, the clear vision can be obstructed by deposits on the optical window such as blood or by fogging. In order to avoid the fogging, a limited improvement can be achieved by preheating the endoscope before using it or even more efficiently by using preheated insufflation gas [3].

Minimal invasiveness

From the intra-abdominal insufflation point of view, the invasiveness can be minimized by applying an intra-abdominal pressure as low as acceptable for performing the procedure. This means especially that any inadvertent overpressurization must be abolished.

Further, the insufflated gas should influence the physiological equilibrium as little as possible. Since the introduction of laparoscopic insufflation, many different gases have been used [4, 5]. For minimizing the risk of embolism, N₂O (nitrous oxide) and CO₂ (carbon dioxide) are preferred due to their high blood solubility. Nevertheless, due to the very common application of electrocautery, the use of N₂O is restricted, because it might cause intra-abdominal combustion. Thus, at the moment, CO₂ remains the gas of choice in spite of its known negative physiological effects, especially when used on older patients with cardiopulmonary diseases [6–10]. As far as alternatives for CO₂ are concerned, the most promising results were achieved with helium, because it is physiologically and physically inactive and also the risk of embolism is reduced due to its high diffusibility [12–15].

On the other hand, recent investigations [16, 17] identify the pneumoperitoneum-related organ dysfunction as being the result of increased intraperitoneal pressure rather than due to hypercapnia caused by the increased CO₂ absorption. The CO₂ may even have an advantage of preventing post-operative infections due to its bacteriostatic effect [18].

An important issue is also the sterility of the insufflation gas. The gas can get contaminated not only with inorganic debris, rust, etc., but also by blood, abdominal fluids and airborne bacteria, when no bacterial filter is used in addition to appropriate precautions [19, 20].

Finally, not only the gas type, but also its physical conditions should match the intracorporal physiological conditions. This means that the insufflation gas should enter the body appropriately preheated to body temperature and vapour saturated [21].

Safety and handling

Furthermore, the requirements for the system's safety and ease of handling are increasing with the development of the laparoscopic insufflation technique from a relatively seldom to a widely used procedure. The expectations of the users are changing; users require an intuitive way of operation and an inherent system safety allowing them to focus on the medical procedure. In addition, the regulatory requirements are becoming more stringent (FDA, MDD / CE, IEC 601, etc.).

The system's safety includes not only a fail-safe design with automatic self check and alert functions, but also smart behaviour. That means that the insufflation will also tolerate irregular treatment conditions such as e.g. gas leakage or other external disturbances of the intra-abdominal pressure. Dangerous conditions such as an incorrect position of the Veress needle or kinked insufflation tubing that cannot be managed by the system itself must be clearly communicated to the user.

The requirements for an easy operation, extended safety functions and an optimal maintenance of the pneumoperitoneum at different working conditions are to some extent contradictory. Also, the additional features for improved performance must not make the device appear more complicated to the user. The surgeon must not get distracted from the patient's treatment by the device. This can be achieved by an optimized man-device interface which does not have to be only limited to the design of the device's front panel, but might also include, e.g. remote control and/or display of vital parameters.

Materials and methods

A new laparoscopic insufflator, the Thermoflator[®] 264320 20 (Figure 1), recently introduced by Karl Storz GmbH & Co. in Tuttlingen, was evaluated under consideration of the medical and technical requirements listed above.

The flow and pressure performance has been tested by means of a worst case set-up (Figure 2) as recommended by ECRI [22]: a 1 l and 3 l i.v. bag was used for abdomen substitute with standard accessories of the tested insufflator (insufflation tubing with 8 mm i.d., length of 2.5 m). The 'intra-abdominal' pressure was measured by a strain-gauge pressure transducer (Type 891.13.590, range 0–250 mbar with Hand-Held Service Manometer 909.40.500, WIKA, Germany). The insufflation flow or leakage respectively was measured by mass-flow transducer (Type F-103D-HB-00-V, range 0.8–40 l/min, Bronkhurst, USA) which was calibrated for ATP conditions (ambient temperature (22°C) and pressure, dry CO₂ gas). For the gas temperature (Pt 100 transducer) and relative gas humidity recording a measuring instrument by Vaisala

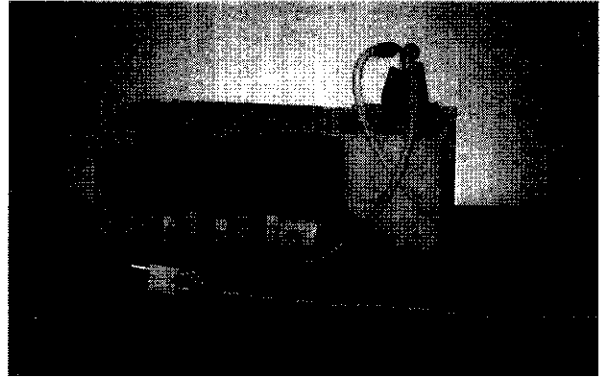


Figure 1. High-flow insufflator with CO₂ gas heating and humidification, the Thermoflator[®] 26 4320 20 with the OptiTherm[®] 20 4320 30 and the CO₂ Humidifier 20 4320 33.

(Finland), Type HM 34, was used. The test set-up is shown in Figure 3.

Results

High-flow capacity

The evaluated insufflator can provide an average insufflation

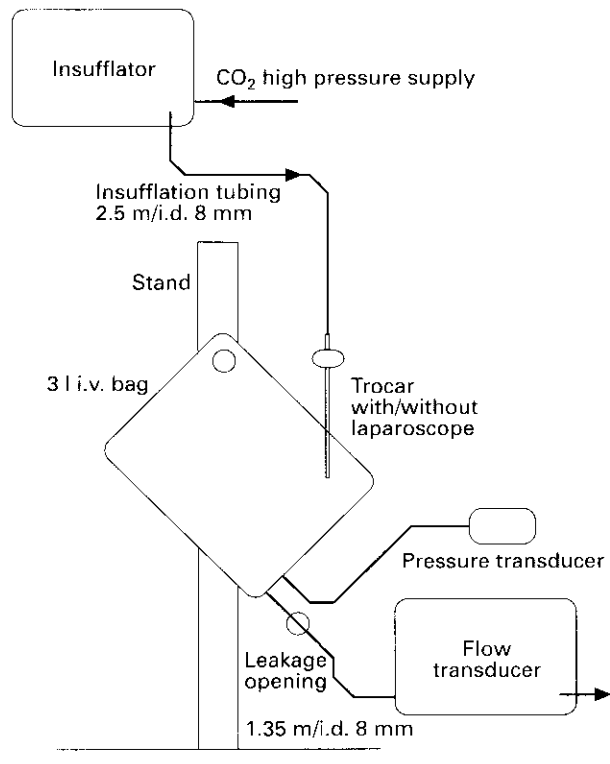


Figure 2. Test set-up for the evaluation of the insufflator performance.

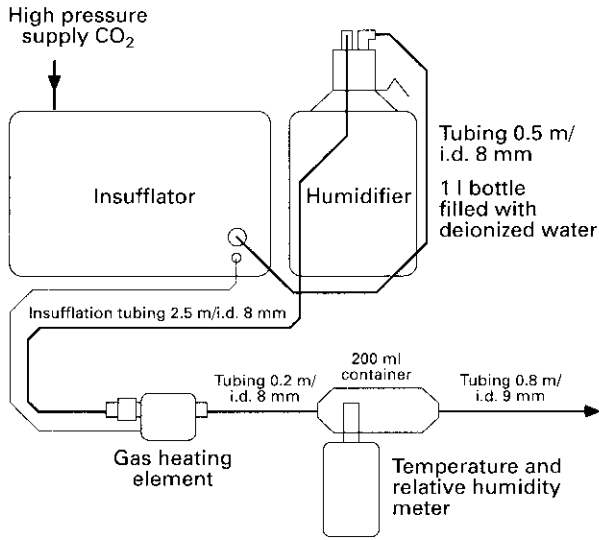


Figure 3. Test set-up for the evaluation of the CO₂ humidifier and the gas heating element.

flow of up to 30 l/min. This flow is sufficient to maintain an intra-abdominal pressure of 10–15 mmHg even in the case of massive gas loss due to aspiration, smoke evacuation, instrument changes, tissue removal or emergency. Figure 4 demonstrates the high-pressure stability. The high-flow capacity allows gas leakage compensation of

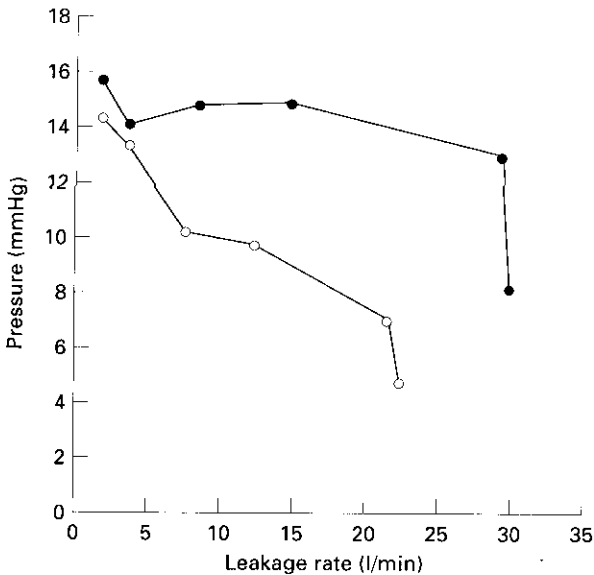


Figure 4. Intra-abdominal pressure as a function of the gas leakage using 3 l i.v. bag according to ECRI test specification [22]. ○, 12 mm trocar with LuerLock (30104 K); ●, 13 mm trocar with hose barb (30107 K). Mode setting: semicontinuous flow; pressure set-point: 15 mmHg; insufflation flow set-point: 30 l/min.

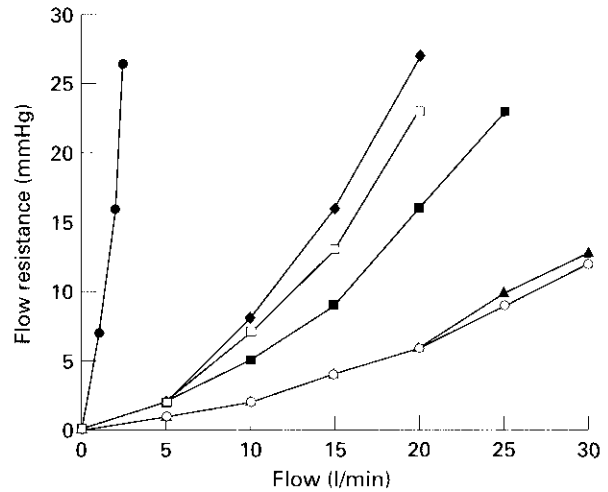


Figure 5. Pressure drop across different patient access instruments as a function of flow. ●, Veress needle 26120 J; ◆, 12 mm trocar with LuerLock (30104 K) and inserted 10 mm laparoscope (26033 APA); ■, 11 mm trocar with hose barb (30103 L) and inserted 10 mm laparoscope (26033 APA); ▲, 13 mm trocar with hose barb (30107 L) and inserted 10 mm laparoscope (26033 APA); □ 12 mm trocar with LuerLock (30104 K); ○ 11 mm trocar with hose barb (30103 L).

over 25 l/min without significantly influencing the intra-abdominal pressure.

The pre-set flow value as well as the displayed actual value are the true average flows. With most of the other insufflators, the pre-set or display value is only the peak flow and the average flow might be as low as 50% of this value depending on the steepness of the flow ramping up and down necessary for the intermittent mode of operation. Furthermore, the connection type between the insufflation line and the instrument (mainly a trocar) is to be considered. Using regular LuerLock connectors, at maximum only an average flow of approximately 18 l/min or less can be reached. Thus, for achieving the specified maximal flow with the safe low insufflation pressure of only 50 mmHg, also the optional HiCap^R trocars and HiCap^R instruments with hose barb connector having reasonably larger lumen compared to the standard LuerLock must be used. Figure 5 shows the pressure drop for different trocar/instrument combinations. It can be easily seen that when using small lumen connectors, reasonably higher insufflation pressures are needed for comparable flow values.

The unit can be operated at two different flow modes:

(1) *Intermittent flow mode (IMF)*

This mode of operation corresponds to the well established method used by the most laparoscopic insufflators on the market. The flow is periodically reduced to zero to measure exactly the intra-abdominal pressure.

(2) Semicontinuous flow mode (SCF)

Contrary to the intermittent mode, the flow is not completely reduced to zero. The flow reduction is sufficient for controlling and monitoring the intra-abdominal pressure with sufficient accuracy. The pressure displayed is a slight overestimation. This means that in this mode of operation, the true intra-abdominal pressure is always smaller than (max. difference < 3 mmHg) or equal to the display value.

When using continuous ventilation for smoke evacuation during CO₂ laser or electrocautery application, the use of semicontinuous mode of operation which provides a better pressure stability at these operating conditions is recommended. Also, a continuous unobstructed visibility is achieved.

Accordingly, a completely safe operation can also be maintained in combination with an ABC by adjusting the leakage to a value slightly larger than the preset maximum argon flow and by selecting the semicontinuous mode. An optimal flow adjustment is easily performed by increasing the leakage until the actual flow is at least 10–20% higher than the preset maximum argon flow.

Further, due to the relatively continuous insufflation flow, the CO₂ laser beam, when applied through the operative laparoscope, remains focused (significant blooming reduction [23]).

This mode of operation also allows the monitoring of the insufflation tubing status. An acoustic and visual (flashing flow display) warning is generated in case of an obstruction (for example kinking) of the insufflation tubing, which cannot be detected with regular (intermittent flow) insufflation systems. Thus, the pressure value displayed and controlled is always well correlated to the intra-abdominal pressure. An inadvertent overpressure situation cannot take place.

Summarizing, the SCF unifies the advantages of continuous flow, the efficiency of the intermittent flow and the simplicity of a single tubing connection between the insufflator and the patient.

Intra-abdominal pressure

An optimized pressure control algorithm maintains a constant intra-abdominal pressure throughout the procedure, independent of the size and elasticity of the peritoneal cavity, instrumentation used and a large amount of gas leakage. Our measurements showed that this new algorithm guarantees not only a very good stability of the intra-abdominal pressure (Figure 4), but also a minimal overshoot (Figure 6) even with relatively small intra-abdominal cavities (paediatrics) during primary filling. For

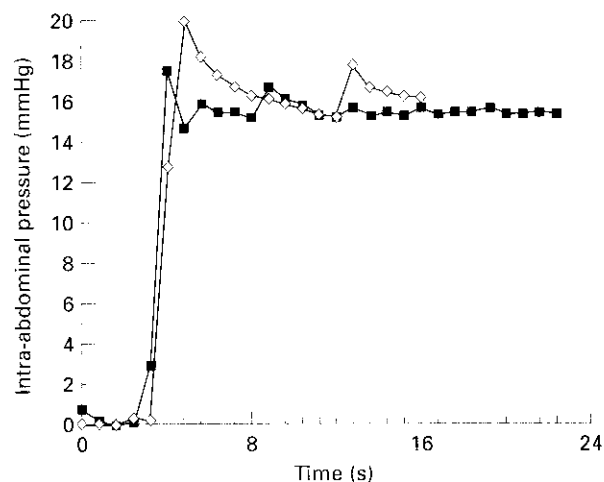


Figure 6. Intra-abdominal pressure as a function of time with two intra-abdominal cavity models (3 l (■) [22] and 1 l (◇) i.v. bag respectively). For access a 13 mm trocar with hose barb (30107 L) and inserted 10 mm laparoscope (26033 APA) have been used. Mode setting: intermittent flow; intra-abdominal pressure set-point: 15 mmHg; insufflation flow set-point: 30 l/min.

these tests, worst case conditions were applied by using a relatively stiff intra-abdominal cavity model in accordance with the ECRI testing set-up [22]. When using an elastic cavity model which is closer to the *in-vivo* conditions, the pressure deviations get even smaller.

Additionally, the Secuvent^R system, an electronically controlled venting valve, guarantees that, in case of overpressure generated by an external means (mechanical force against the abdomen, argon gas insufflation (ABC) or similar), it is reduced to a physiologically acceptable preset value within 5 s.

Insufflation pressure

In spite of the high flow performance, the maximal insufflation pressure at unit output never exceeds 50 mmHg. Additionally (see below), with the initialization mode, an insufflation at very low insufflation pressure (10–30 mmHg) can be performed.

Gas heating and humidification

In order to minimize the negative thermal effect by insufflating a large volume of dry and cold (ambient temperature) gas, our insufflator is fitted with an effective heating element, the OptiTherm^R, which is autoclavable and can easily be applied close to the insufflation port for optimal efficiency.

It can be shown on behalf of experimental data (Figure 7) that due to the cooling down of the gas when passing

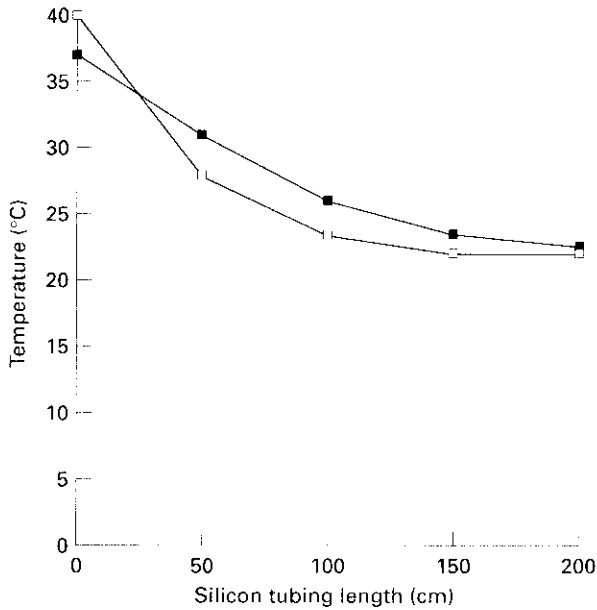


Figure 7. CO₂ gas temperature decrease as a function of insufflation tubing length. Flow: □, 3 l/min; ■, 10 l/min.

through the insufflation tubing, it is not possible to heat the CO₂ gas at the insufflator output. Compared to other solutions, e.g. with heating element distributed along the insufflation tubing, the tested unit uses a small autoclavable heating element placed close to the patient's access. This approach is economical, efficient and allows the use of standard, light (easy handling) and transparent (safety) tubing connection between the insufflator and the patient [20]. Figures 8 and 9 show the good stability and time response

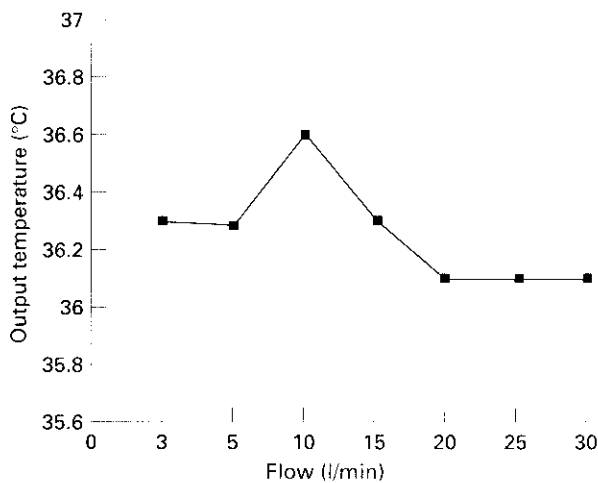


Figure 8. CO₂ gas temperature at the output of the heating element as a function of the flow.

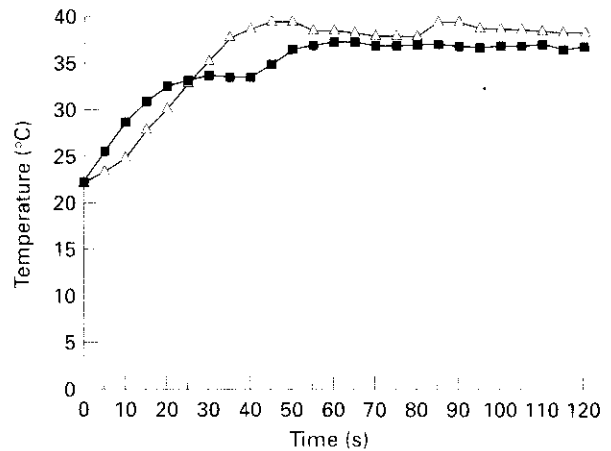


Figure 9. CO₂ gas temperature at the output of the heating element at 5 (△) and 30 (■) l/min and intermittent flow mode as a function of time after power on.

of the CO₂ gas temperature as the function of the flow and time respectively.

Furthermore, an optional CO₂ gas humidifier is provided. Its efficiency is shown in Fig 10. The relative humidity RH is plotted as function of the flow. Without the use of the gas heating element, a significantly higher relative humidity of approximately 90% can be achieved compared to the combination with the heating element with approximately 65%. On the other hand, without this additional heating the temperature of the humidified CO₂ gas does not come close enough to the body core temperature.

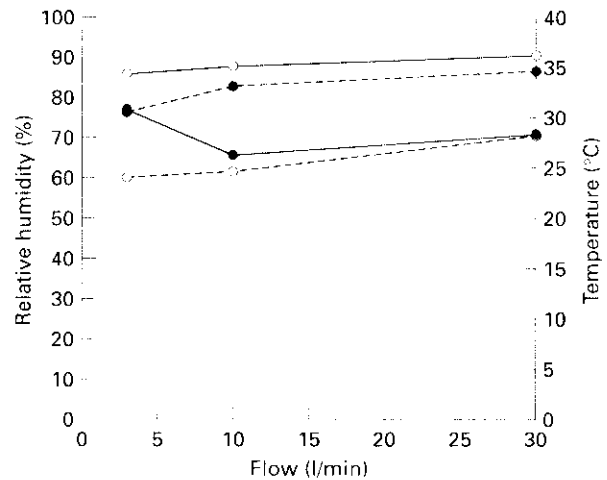


Figure 10. CO₂ gas temperature (dotted line) and relative humidity (solid line) at the end of the insufflation tubing as a function of the flow, with the CO₂ humidifier and with/without the gas heating element. ○, Without OptiTherm; ●, with OptiTherm.

Pneumoperitoneum initialization

The safe placement of the Veress needle, prior to the initial insufflation into the peritoneal cavity, is still not completely without risk. The evaluated insufflator offers monitoring features, which are generally known and established, but usually afford additional or different tools. During the initialization mode, there is a continuous insufflation flow providing the following monitoring and safety features:

- Continuous measurement of the insufflation pressure. This pressure value is identical with the intra-abdominal pressure, when there is no insufflation flow (e.g. insufflation switched-off). This allows the negative pressure, which is a good indicator for the Veress needle tip to be correctly placed within the intra-abdominal cavity, especially when lifting the abdominal wall, to be immediately displayed. Also, pressure variations due to the respiration can easily be recognized.
- An acoustic and visual (flashing pressure display) indication of rapid pressure rise (10 mmHg/s). This results when the tip of the Veress needle is within the tissue or a small cavity formed by tissue adhesions, or when the insufflation tubing gets occluded.
- It is to be considered that this mode of operation is generally not favourable for rapid and complete filling of the intraperitoneal cavity. Thus, after the correct placement of the Veress needle is verified and 1 or 2 l of gas are insufflated without restrictions, a switch over to the intermittent mode of operation with higher flow setting is recommended. Nevertheless, due to the high flow resistance of the Veress needle, a flow of 2–3 l/min cannot be practically exceeded.
- Constant flow insufflation at very low insufflation pressure (CLIP).

The default setting for the initialization mode is an insufflation pressure of 15 mmHg and an insufflation flow of 1 l/min. At this mode of operation the insufflation pressure at the device output never exceeds the preset value. Thus, it is a very safe setting which can be used favourably for critical cases. Additionally, the default values can be modified by the user for further optimization. Nevertheless, for security reasons, the changes are not memorized, when the unit is switched off.

Safety

The insufflator is fitted with a significant number of security features which allow the user to concentrate on the medical procedure:

Internal fail-safes:

- Self-check (including pressure transducer and RAM

check at power-on and automatic repeated check of the temperature transducers during operation),

- Redundant pressure control by two independent pressure transducers,
- Active venting system
The venting valve can be de-activated (visual indicator) to minimize the risk of unit contamination when no hydrophobic bacterial filter can be used,
- Redundant security blow-off valves (for high and low pressure regulator),
- Redundant temperature monitoring by two independent temperature transducers.

Alarm functions:

- Visual and acoustic redundant (software and hardware) overpressure alarm,
- Visual and acoustic negative pressure alarm,
- Visual and acoustic alarm for low CO₂ gas supply pressure,
- Visual and acoustic redundant over-temperature alarm
The heating is switched off automatically by an independent circuit and the insufflation with unheated gas can immediately be proceeded after the defect heating element is disconnected from the unit.

In addition to the functional safety features mentioned above a disposable hydrophobic bacterial filter is provided to avoid insufflator contamination by inadvertent backflow of body fluids. Its low flow resistance allows unrestricted high flow insufflation.

Handling

In spite of the number of functions available, the unit is still easy to use. In addition to the function keys for adjustment of the insufflation flow and intra-abdominal pressure, as well as the reset-key for the gas volume used and the insufflation activation key, there are only two additional keys for the following function modes:

- M-key for selection of the insufflation mode (semicontinuous and intermittent flow) and for activation/deactivation of the Secuvent^R system (by pressing for more than 2 s),
- initialization-key for activating the initialization mode with continuous gas flow (verification of the Veress needle placement, CLIP insufflation).

The unit is not only fitted with a universal power supply (100–240 VAC), but also with a versatile CO₂ input with US standard connection directly at the unit and a variety of alternative connections (PIN-Index, DIN, ISO or low pressure central gas supply) by means of adaptor hoses.

The unit can be optionally fitted with SCB (Storz Communication Bus) interface which provides the following functional features:

- Display of selected insufflation parameters at selected position within the endoscopic image. This also includes the monitoring of the gas temperature and the low supply pressure alarm.
- Remote control of all device parameters via PC also from sterile operation field.
- Down-load of user and procedure specific insufflation parameters at the beginning of the treatment.
- Pre-programmable display of selected parameters and control elements for on-line control and monitoring. This set-up allows the combination of important parameters from different devices in one display.
- Further functions such as trend display parameter and patient data documentation will be added in the future.

Discussion

The presented evaluation demonstrates that our unit fulfills the basic medical and technical requirements in such a way that it can be considered suitable for any laparoscopic treatment today and in the near future.

This shows that the advanced technology and micro-electronics available today can provide solutions for any requirement that might arise during the development of the operational techniques. On the other hand, as far as the physiological conditions and interactions are concerned, there is still need for further investigations.

As to increasing the gas flow capacity, one has to consider that the insufflated CO₂ gas enters the body dry and at ambient temperature, i.e. cold, compared to the body temperature. This gas interacts within the body with a relatively large surface area of the intraperitoneal mucosa (approx. 2 m² [24]). Thus, the gas desiccates and cools the tissue by warming up to the body core temperature and by getting close to being saturated with vapour. Animal experiments [25] showed that the relative humidity of the CO₂ gas is at the range of 80–90% when escaping from the abdominal cavity. Investigations performed by Ott [24, 26] revealed a body core temperature decrease of 0.5°C at flow rate of only 7 l/min. Currently, there are still controversial opinions as to whether the heat loss due to the CO₂ insufflation leads to hypothermia or to other negative physiological effects.

Still, even simplified theoretical evaluation provides results supporting the opinion that the pre-heating and humidifying of the CO₂ gas should be beneficial to the patient. With the help of basic physical data [27] (pressure can be considered as constant) it can easily be shown that,

for heating CO₂ gas from the ambient temperature (on average 22°C) to the body temperature (37°C), i.e. $\Delta T = 15^\circ\text{K}$ at a mean flow $Q_m = 20$ l/min, a heat power of approximately 8 W is needed:

$$P_1 = \rho c_p Q_m \Delta T = 7.62 \text{ W}$$

with ρ (22°C) = 1.823 kg/m³ (specific gravity), and
 c_p (CO₂) = 0.837 kJ/kgK (specific CO₂ heat capacity).

Assuming further that the CO₂ gas is not only heated up to the body core temperature, but also getting vapour saturated, reasonably higher power of approximately 40 W due to the energy needed for water evaporation is additionally necessary at conditions mentioned above:

$$P_2 = (1 + \gamma \Delta T) Q_m f_{\max} r \approx 39.7 \text{ W}$$

with γ (CO₂) = 0.003726/K (volume expansion coefficient),
 f_{\max} (37°C) \approx 50 g/m³ (maximal absolute humidity), and
 r (water) = 2256 kJ/kg (specific evaporation heat).

When these results are compared with the basic metabolism needed for maintaining the body core temperature of a non-moving person amounting to approximately 100 W [28], the previously mentioned results regarding hypothermia appear more reasonable. These estimative results coincide very well with even more detailed theoretical and experimental investigations [25].

The significance of the effects described can easily be recognized when one remembers how warm wind blowing over one's wet skin feels cold. A local magnifying effect of the hypothermia might be expected due to the locally reduced heat loss compensation as a result of restricted blood circulation caused by increased intra-abdominal pressure. Considering further that, for artificial ventilation, heating up and humidifying the gas is a state-of-the-art, one might be astonished to learn that it is not yet generally required for high flow CO₂ insufflation.

Meanwhile, there are clinical studies [29–31] showing that pre-heating of the insufflation gas results in a significant reduction of post-operative pain. It was further observed that desiccations of abdominal tissue might increase the possibility of adhesion formation [32]. It can be expected that the additional humidification might have more significantly positive physiological effects.

Also, the choice of the insufflation gas is not finally optimized. There are further investigations with argon gas and of course, also the alternative of gasless laparoscopy should be mentioned. Nevertheless, this approach will also only remain an alternative for selected cases [33].

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