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Real-time assessment of colonic gases using a new medical device

Anna Orsatti[1], Giorgio Ciprandi[2], Marino Carnovali[3]

[1] *Medical Affairs, NTC, Milan, Italy*
[2] *Casa di Cura Villa Montallegro, Genoa, Italy*
[3] *Ospedale Papa Giovanni XXIII, Bergamo, Italy*

ABSTRACT

Background and aim: Knowing the composition of intestinal gas is important in clinical practice. Dangerous hydrogen and/or methane concentrations could be created during a colonoscopy. Therefore, it was desired to develop a portable gas detector that could provide real-time information on oxygen, hydrogen, and methane concentrations during a colonoscopy procedure.

Methods: The tested device was set up by Dräger and was evaluated in different laboratory settings.

Results: The results showed the reliability of this device. Namely, the device correctly measured H_2, O_2, and CH_4 concentrations.

Conclusions: The device studied can be used in comparative clinical studies to compare the impact on colonic gas concentration by different intestinal preparations.

Keywords: Bowel, intestinal gases, gas detector, colonoscopy.

Correspondence: Giorgio Ciprandi - Via Paolo Boselli 5, 16146, Genoa, Italy - Tel 390103627986 - E-mail gio.cip@libero.it

INTRODUCTION

Colonic explosion, extremely rare during colonoscopy, requires three factors: high concentrations of combustible gas (H_2 and/or CH_4) and comburent O_2, and application of heat, electrocautery, or argon plasma coagulation [1-3]. Other factors include gastrointestinal disorders and bowel preparation for colonoscopy, both may increase H_2 and/or CH_4 [4-7]. Indeed, the drug used for preparation may affect gas pattern, but other factors may increase combustible gases [8]. These factors include diet, personal microbiota, enteric motility, cleanliness degree, age, comorbidity, concomitant medications, and preparation quality [9]. Anyway, reliable information about the gas composition may be helpful during a colonoscopy. Namely, an unmet need is to have a system for measuring intestinal gas during the colonoscopy performance, so providing real-time information to the doctor regarding the presence of potentially critical gas concentrations. Additional information is the relationship between preparation and gas concentration.

An ideal system should simultaneously measure H_2, CH_4, and O_2. This system could also inform on the effective gaseous exchange between the intestinal lumen and the external environment, suggesting an adequate elimination of potentially dangerous concentrations of colonic gases during colonoscopy. Gas chromatography has been used to measure gas concentration during colonoscopy, but the information does not occur during the procedure. As a result, alternative devices have been developed to satisfy this unmet need.

Recently, the detector Dräger has been used to precisely measure intestinal CH_4 in real-time [8]. This gas detector is equipped with an automatic suction system and connected to a plastic catheter introduced into the working channel of the colonoscope.

The present study investigated another new gas detector derived from the previous device.

MATERIAL AND METHODS

The Dräger X-am 8000 multi-gas detector was tested to verify the suitability and precision in measuring H_2, CH_4, and O_2 ***(Figure 1)***. Therefore, laboratory tests were carried out before its clinical application. For this study, the detector was fitted with the following gas sensors:

1) Dräger Sensor XXS O_2 measures O_2 from 0 to 100% vol. with a resolution of 0.5% vol.

2) Dräger Sensor XXS H_2 HC measures H_2 from 0 to 4% with a resolution of 0.5% vol.

3) Dräger Sensor XXS IR EX measures methane (CH_4) between 0-100% vol. lower explosion limit (LEL) with a resolution of 0.2%vol.

The sensors use different physical principles for the determination of the individual gases (absorption of infrared radiation for CH_4 and H_2, partial pressure measurement for O_2), and operate independently of each other. Therefore, the measurement made by one sensor for a specific gas does not affect the measurements made simultaneously by the other sensors for the other gases, even in the event of a malfunction.

Figure 1.
Picture of gas detector system

The range of measurements of each sensor is consistent with the inclusion of potentially dangerous concentrations.

The Dräger X-am 8000 multi-gas detector has been connected through an anti-dust and anti-humidity filter, a three-way faucet valve, and a connector to an ERCP cannula. This cannula conveys gases from different colon segments to the detector to measure their concentrations.

The experimenter drew the volume of gas necessary for the analysis from the catheter by shifting the lever of the three-way faucet valve. Once the gases were removed from the detector, they could not return to the patient and were available for measurement. Gas concentrations inside the colon were thus shown in real time on the detector display.

To assess the reliability and precision of the system, it has been evaluated as more appropriate to proceed with a risk assessment evaluation addressing requests listed in annexes C and E of the UNI CEI EN ISO 14971: 2012. Once that possible risks and hazards have been identified, there were estimated and evaluated using a Failure Mode and Effects Analysis (FMEA). The only risk identified through the analysis was the electric potential risk inherent in all devices with a battery. In addition, an external certified laboratory measured the amount of energy dissipated by the cannula with the detector per ISO 62353. This test was conducted by the Clinical Ingegnery of the Hospital Niguarda (Milan, Italy).

Once the device's security was assessed, it was verified that the devices connected to the detector did not alter their measurement capabilities. The Dräger device primarily determines ambient gases, i.e., gas measurement at potentially explosive environmental concentrations. Potentially explosive concentrations depend on the concentrations of H_2 and CH_4 in the presence of O_2, whereas they are independent of the environment where the concentrations are measured. Therefore, the potential risk depends only on the gas concentrations, wherever these are present. Therefore, there is a close analogy between the measurement of ambient and colonic gases; thus, the use of the detector in the clinical protocol is consistent with the primary intended use of the system itself. For this reason, it was not considered necessary to re-evaluate the meter's accuracy and safety but to assess the risks of the detector connected to the medical devices designed to convey gases from the colon to the detector.

A cause that could lead to incorrect measurement by the detector was the presence of possible leaks at the connections between the various medical devices connected to the Dräger X-am 8000 multi-gas detector. Moreover, other issues may occur between the filter and the three-way valve, the valve and the connector, and the connector and the ERCP cannula. Therefore, the method was investigated with an external laboratory to demonstrate the absence of any gas leaks between the connections. A test was developed in which the various medical devices were connected and placed in a glass beaker with water; to test the system in a worst-case scenario, the set of devices was connected to an air compressor. When the air compressor was activated, the air suction towards the detector was automatically switched on. Any gas leaks would lead to visible bubbles inside the beaker. The test was repeated three times. The test was performed at laboratory Tecnolab del Lago Maggiore (Verbania Fondotoce, Italy).

The last check that was carried out related to the stability of the measurement and how long it was necessary to wait for a stable measurement from the detector. Moreover, the test has helped to demonstrate that the system's configuration allows precisely measuring a gas mixture with known concentration. The environmental gas detector is usually used in continuous aspiration. It has a response speed certified by the manufacturer according to the length and diameter of the tube used to aspirate the gases. Rather than a tube provided by the manufacturer, an ERCP catheter with an internal diameter of 1 mm and several interconnected medical devices were used, therefore was fundamental to understand how long to wait after the aspiration starts to achieve a stable measurement. In addition, it was important to know how long to wait between one measure and the next to prevent the first from influencing the value of the second. It was crucial to share this information with the clinicians involved in the clinical trial to know how long to wait during

the measurements to ensure the data was collected. This information has been collected with the aim of a specialized external laboratory, which timed the time taken to stabilize the measurement using the system described above. To best challenge the measurement system, tests were carried out using three different mixtures for each gas at increasing concentrations: methane mixtures foreseen 2%, 22,5%, and 45% of the LEL; hydrogen mixtures used were at concentrations of 0.08%, 3.25%, and 44%. Each measurement has been performed four times. This test has been run at Mavetec laboratories (Massanzago, Italy).

RESULTS

ELECTRIC DISPERSION

The test resulted in a measure of Alternating Current and Direct Current of 2,3 µA. The high limit foreseen by the procedure is 5000 µA.

SEALING OF THE FITTING

The sealing test was carried out with three sets of disposable medical devices. No air leakage was detected from any of the system's connection points. The results are detailed in *Table 1A.*

Table 1A - Sealing test findings

Test n°	Result
1	no air leak
2	no air leak
3	no air leak

Table 1B - Time needed to reach a stable value of known mixtures of gases through the system

Conc. Referring	Transit time				
	First measurement	Second measurement	Third measurement	Fourth measurement	Average
45% LEL CH_4	22 sec	23 sec	23 sec	24 sec	23 sec
22.5% LEL CH_4	31 sec	32 sec	31 sec	30 sec	31 sec
2% LEL CH_4	36 sec	37 sec	38 sec	37 sec	37 sec
Total average					30.3 sec

Conc. Referring	Transit time				
	First measurement	Second measurement	Third measurement	Fourth measurement	Average
44% LEL H_2	25 sec	27 sec	26 sec	26 sec	26 sec
3.25% LEL H_2	28 sec	29 sec	29 sec	28 sec	28.5 sec
0.08% LEL H_2	30 sec	32 sec	31 sec	33 sec	31.5 sec
Total average					28.7 sec

MEASUREMENT TIME AND STABILITY

The system maintains a constant flow to have a fast response time. Test measurements collected are presented in detail in *Table 1B*.

DISCUSSION

The electrical leakage test showed that the only point that potentially comes into contact with the patient, namely the tip of the catheter, has a practically negligible value, causing no risk to the patient or the operator.

Concerning the tests on the possibility of dissipation of the gas taken inside the colon and conveyed to the detector for measurement, the leak test revealed no dispersion of air and gas.

Although the detector is connected to various medical devices, its measurement accuracy, demonstrated through tests on a known volume mixture of gases, was not affected.

The device maintains a constant flow to have a fast response time (around 30 sec for all the measurements) and pressure stability inside the cell of diffusion of the gas, thus making the sensors work in the best condition, guaranteeing a reliable response to the value read. Based on that data, endoscopists have to wait 30 sec for each measurement to reach a stable value.

CONCLUSIONS

This new gas detector seems to be reliable as the various tests on the gas detection system did not reveal any criticalities regarding safety or measurement reliability. Moreover, the device easily and quickly continuously measured gas levels in real-time. Therefore, this new gas detector could be appropriate for being used in clinical trials exploring the safety and efficacy of new bowel preparations.

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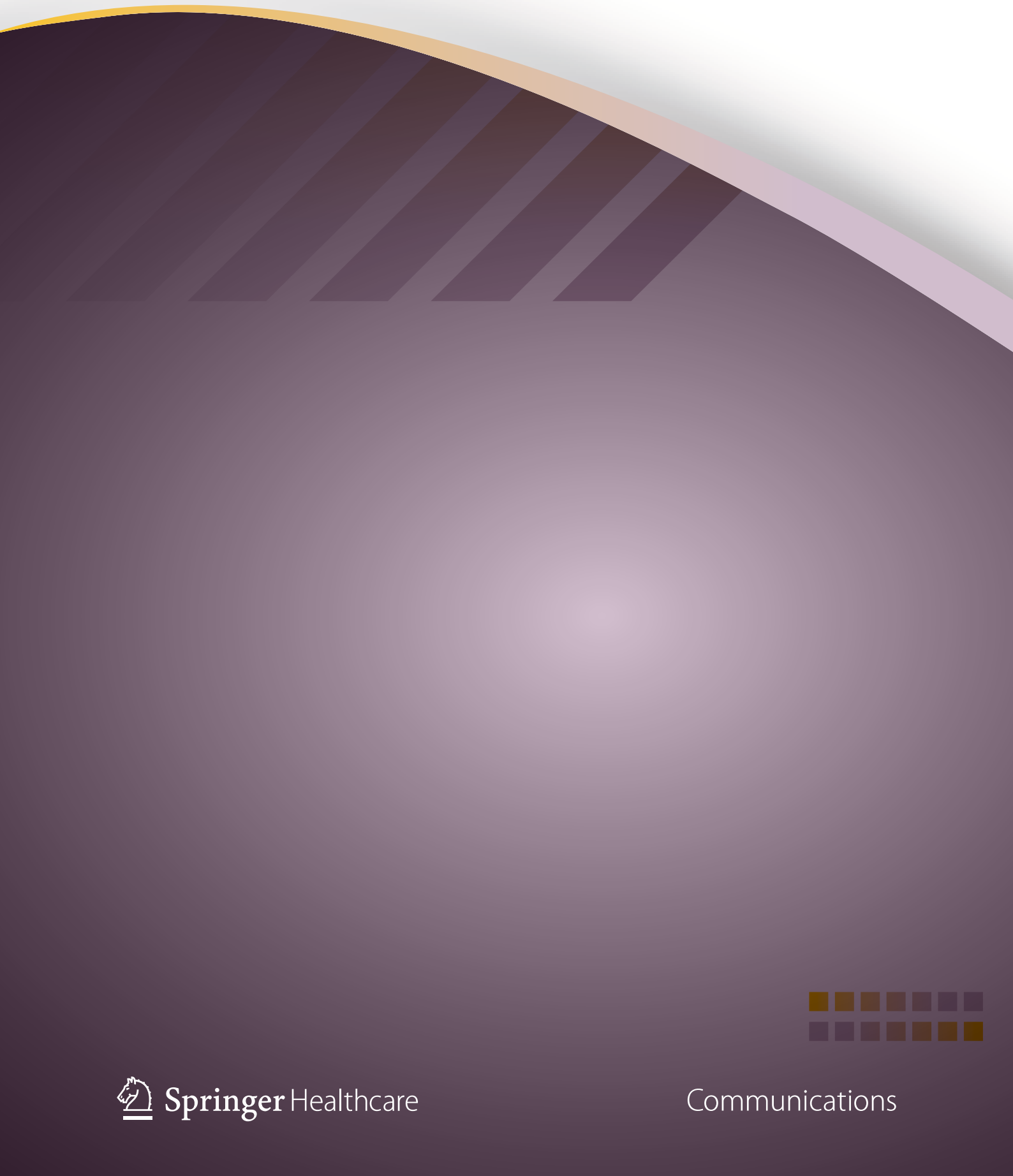

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