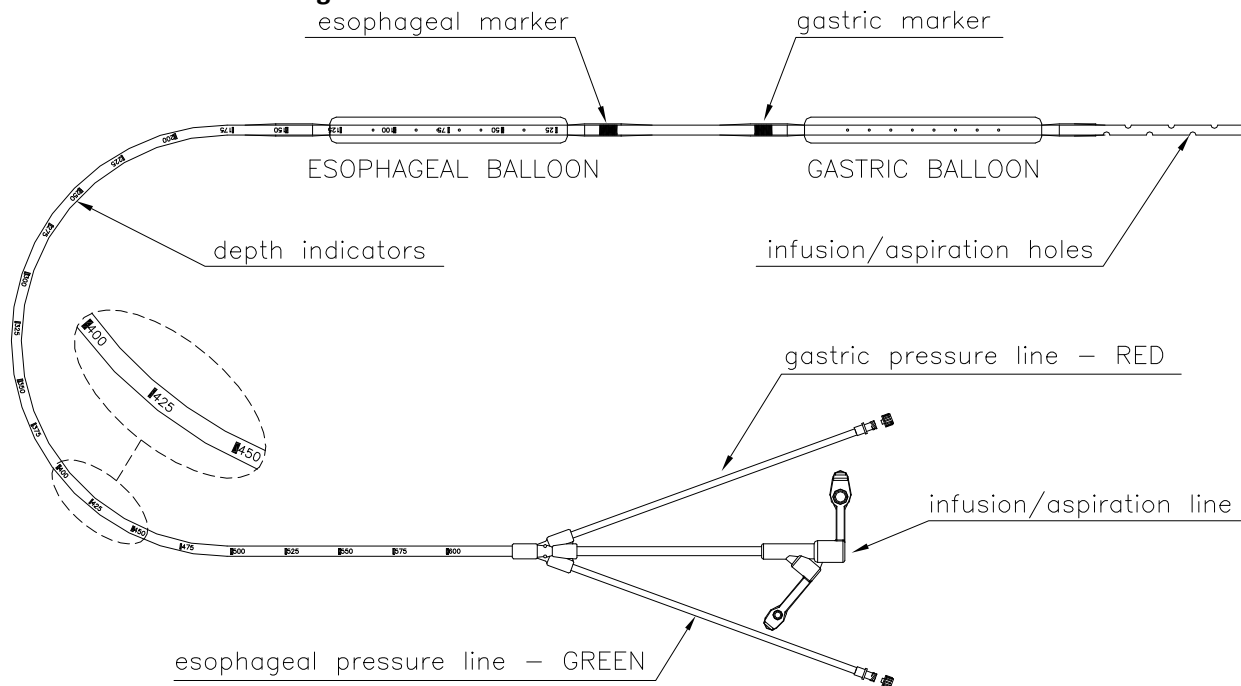


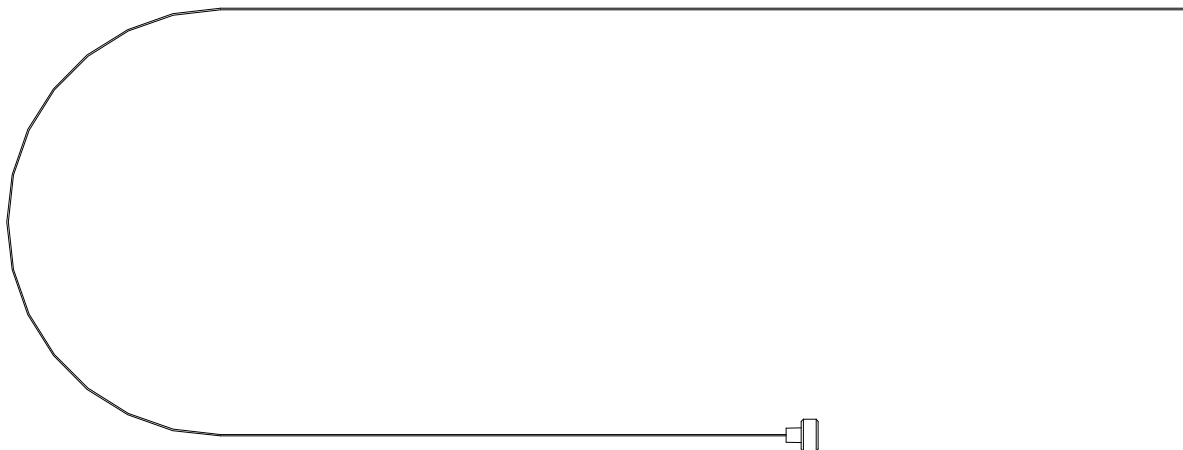
NUTRIVENT™ MULTIFUNCTION NASO-GASTRIC CATHETER

CONTENT OF THE BOX

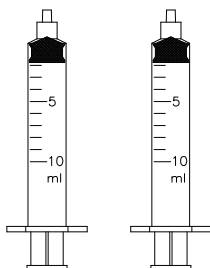
Nutrivent™ multifunction naso-gastric catheter



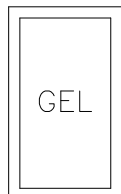
Metallic wire for insertion



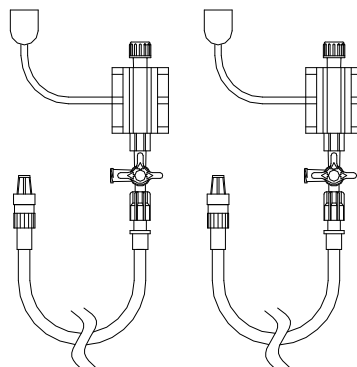
Syringes



Lubricating gel



Pressure transducers



The NutriVent™ multifunction naso-gastric catheter is a polyurethane catheter provided with two polyethylene balloons suitable for registering the esophageal and gastric pressure. The NutriVent™ catheter is flexible, nontraumatic and can also be used for long periods (maximum 30 days). The package includes a metallic wire for the insertion, the lubricating gel (for the catheter and for the metallic wire). Two 10 ml syringes for the balloon blowing and two Medex pressure transducers. The NutriVent™ catheter can be directly connected to a monitor as well as to a mechanical ventilator, if provided with specially-designed ancillary input for pressure registration.

INDICATIONS

The NutriVent™ probe is suitable for all the conditions where it is necessary to measure / monitor the esophageal and gastric pressure in the adult patient. The esophageal and gastric pressure is essential for a correct management of the ventilation of the critical patient.

Furthermore, the NutriVent™ catheter has all the functions of a normal feeding naso-gastric catheter.

ADVANTAGES

- Single catheter
- Continuous measurement and monitoring of the esophageal and gastric pressure
- Does not need other medical device and there is no risk of urinary tract infection

CONTRAINDICATIONS

- Uncontrolled coagulopathy
- Serious plateletpenia
- Nasal traumas
- Esophageal varices

WHY AND WHEN TO MEASURE THE ESOPHAGEAL AND GASTRIC PRESSURE

The measurement of the esophageal pressure is advisable:

- 1) during mechanical ventilation in the patients with acute respiratory failure (example cardiogenic and non cardiogenic lung edema), in order to avoid the damages induced by the ventilator (VILI)
- 2) during non invasive ventilation, to evaluate the respiratory effort of the patient and his capacity of tolerating the non invasive ventilation itself

Esophageal and damage induced by the ventilator

It is well known that 30 cmH₂O of *Aerial tract pressure* (P_{aw}) read on the ventilator represent the threshold for the *damage induced by the ventilator* (VILI). However, the real cause of pulmonary damage is the excessive transpulmonary pressure, greater than 15-20 cmH₂O. The *Transpulmonary pressure* (P_L) is the pressure fraction of the aerial tracts, which is “spent” for stretching the lung, the remaining fraction is the *Pleural pressure* (P_{pl}), which is spent for stretching the chest wall with an equivalent volume. As the direct measurement of the *Pleural pressure* (P_{pl}), is not possible in the clinical practice, the *Esophageal pressure* (P_{es}) will be used. This one has proved to be a good indication.

In formula:

$$\Delta P_{aw} = \Delta P_L + \Delta P_{pl}$$

This equation represents the “fractioning of the respiratory mechanics”.

Then, by measuring the esophageal pressure, you can calculate the transpulmonary pressure (i.e. $\Delta P_L = \Delta P_{aw} - \Delta P_{es}$). It has been proved that the airway pressure is an unsuitable surrogate of the transpulmonary pressure⁽¹⁾: in fact, very low transpulmonary pressures can match to the same airway pressure of 30 cmH₂O. This is due to the variability of the elasticity of the chest wall.

Let's take the following cases into consideration:

Case 1: $\Delta P_{aw} = 30 \text{ cmH}_2\text{O}$ and $\Delta P_L = 7 \text{ cmH}_2\text{O}$

In this situation 23 cmH₂O of pressure are spent for stretching the chest wall and only 7 cmH₂O for stretching the lung. This transpulmonary pressure can be insufficient for a suitable gaseous exchange.

Case 2: $\Delta P_{aw} = 30 \text{ cmH}_2\text{O}$ and $\Delta P_L = 28 \text{ cmH}_2\text{O}$

In this situation, only 2 cmH₂O are spent for stretching the chest wall and 28 cmH₂O for stretching the lung. This transpulmonary pressure is close to the pressure, which is registered at the maximum respiratory capacity of the lung and is surely able to induce irreversible damages in the lung.

Both in the **Case 1** and in the **Case 2** the physician reads an airway pressure of 30 cmH₂O, therefore, it is the esophageal pressure, which allows to discriminate the two conditions and to modify, as a result of this, the mechanical ventilation. In the first case, in fact, exceeding the 30 cmH₂O in the aerial tracts to assure a suitable ventilation, does not involve additional risks, as the transpulmonary pressure would remain within the safety limits, while, in the second case, the tidal volume or the PEEP should be reduced to bring back the transpulmonary pressure within the safety limits (lower than 15-20 cmH₂O).

Esophageal pressure and compliance/elastance

The *Compliance* (C) and its mutual, *Elastance* (E), are measurements of the extensibility of a mechanical structure and are extremely useful in the characterization of a patient with acute respiratory failure.

$$Compliance = \frac{\Delta V}{\Delta P}$$

$$Elastance = \frac{\Delta P}{\Delta V}$$

In the acute respiratory failure, the compliance is strictly related to the lung quantity, which can still be ventilated. In the normal adult, the compliance is about 100 mL/cmH₂O: a compliance of 50 mL/cmH₂O indicates that only 50% of the original lung is still available to the ventilation (the remaining is collapsed or consolidated); a compliance of 20 mL/cmH₂O indicates that only 20% of the original lung is still available for ventilation, and so on. Therefore, the compliance measurement provides an idea of the dimensions of the lung available to ventilation (baby lung). Obviously, if after maneuvers of lung recruitment the dimensions of the lung available to ventilation increases, also the compliance will increase as a result of this.

In an adult patient, with compliance values between 40-50 mL/cmH₂O, the ventilation with current low volumes with PEEP is still within the safety limits, while under 30 mL/cmH₂O we are in an area of actual risk of damage induced by the ventilator.

To better characterize this risk it is better to report to the components of the respiratory system (lung and chest wall) and use the elastance concept.

The elastance of the respiratory system is the pressure necessary for stretching of 1 liter both the lung and the chest wall, the pulmonary elastance is the pressure necessary for stretching only the lung, while the thoracic elastance is the pleural pressure necessary for stretching the chest wall. Then, the elastance of the respiratory system is given by the addition of the lung elastance and of the chest wall.

In a healthy individual and in spontaneous breath, the elastance of the chest wall and of the lung are equivalent. In the same individual, but supine and sedated, the elastance of the chest wall and of the lung are not equivalent anymore (see Table 1), but their ratio becomes, averagedly, of 2 to 1, therefore the pressure necessary for stretching the lung is about the double compared with the one of the chest wall. This datum represents, however, an average

value and, unfortunately, the ratio between the elastance of the lung and of the chest wall is subject to an extreme variability, which can be different both in healthy individuals or patients.

Therefore, the measurement of the compliance / elastance of the lung is essential for a correct clinical management of the patient.

Esophageal pressure and non invasive ventilation

During the non invasive ventilation, the monitoring is limited to the registration of the *Airway pressure* (P_{aw}) and to the respiratory frequency, as it is not an accurate measurement of the *Tidal volume*, which effectively ventilates the patient (for example due to possible losses and/or high compliance of the mask or of the helmet).

The calculation of the esophageal pressure through the measurement of the esophageal pressure enables us to evaluate the effectiveness of non invasive ventilation and the possible risk of respiratory fatigue.

In healthy individuals, during the normal ventilation, the esophageal pressure oscillates between -2 and -5 cmH₂O during inhaling.

Therefore, if the esophageal pressure oscillates between the -2 e -8 cmH₂O and the respiratory frequency is lower than 25 acts per minute, we can affirm that the patient can tolerate the non invasive ventilation suitably. Otherwise, if the esophageal pressure exceeds the -10 cmH₂O, we know that the effort the patient is doing is extremely high and he will not be able to tolerate it for a long time. Therefore, the only registration of the airway pressure is not suitable for a correct clinical management of the patient.

Gastric pressure

The abdominal pressure, under normal conditions, when the abdominal muscles are normally stretched and the bowels of normal dimensions, is approximately equivalent to the pressure we should have if the abdomen were full of water, Under these conditions, the pressure exerted in any point of the abdomen in the ventrodorsal direction is given from the height of the overtopping water column multiplied by the liquid density, which is equivalent to 1 for water.

If, for example, the abdomen walls become more rigid and/or the volume of bowels increase, the abdominal pressure will increase and all the structures subject to this pressure will modify their status. The diaphragm will move in cranial direction, the pulmonary volumes will be reduced, the splanchnic perfusion will decrease with worsening of the gastrointestinal, hepatic and renal function.

In the clinical practice, the abdominal pressure can be estimated by the measurement of the gastric pressure or of the vesical pressure. The measurement of the gastric pressure allows the measurement of the abdominal pressure by avoiding infection risks, if any, of the urinary tracts; these risks might occur by using the measurement of the vesical pressure and under all those conditions where it is contraindicated or impossible to use the vesical pressure (absence of urinary catheter, major pelvic trauma).

OPERATING INSTRUCTIONS

Insertion of the NutriVent™ multifunction naso-gastric catheter

- 1) Place the patient in supine or in half-sitting position.
- 2) Anaesthetize the nasal cavity and the mouth with 4% spray lidocaine.
- 3) Lubricate the metallic wire abundantly with the lubricating gel and insert it inside the NutriVent™ catheter up to the distal end.
- 4) Lubricate the NutriVent™ catheter abundantly with the lubricating gel all along.
- 5) Insert the NutriVent™ catheter in the rear nasal cavity through the nostril and make it move forward in the esophagus and in the stomach up to reach a depth of 40-42 cm (**Figure 1**).
 - ⚠ **If the patient is conscious, ask him to swallow during the passage of the NutriVent™ catheter in order to make it move forward easier.**
 - ⚠ **During insertion, check that the NutriVent™ catheter does not wrap in the oral cavity.**

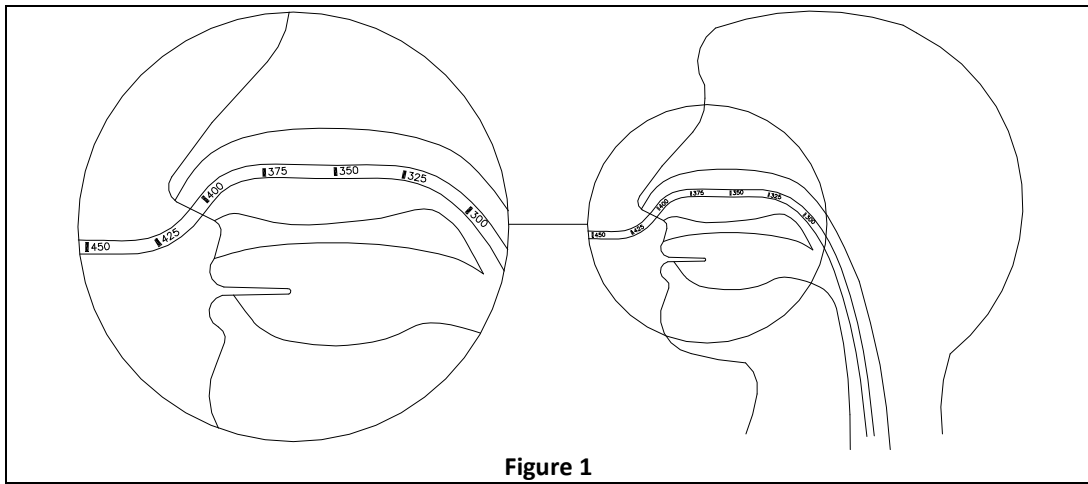


Figure 1

- 6) Unthread the metallic wire softly.
- 7) Fix the NutriVent™ catheter to the nose with plaster.

Connection to the monitor and calibration

- 1) Connect the pressure line you want to read (esophageal or gastric) to a pressure transducer provided with a three-way stopcock with luer-lock (Figure 2).

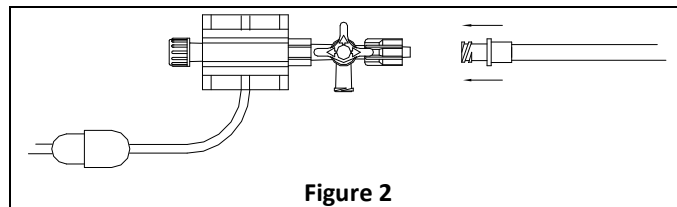


Figure 2

- 2) Connect the pressure transducer to the monitor through the dedicated cable (Figure 3).

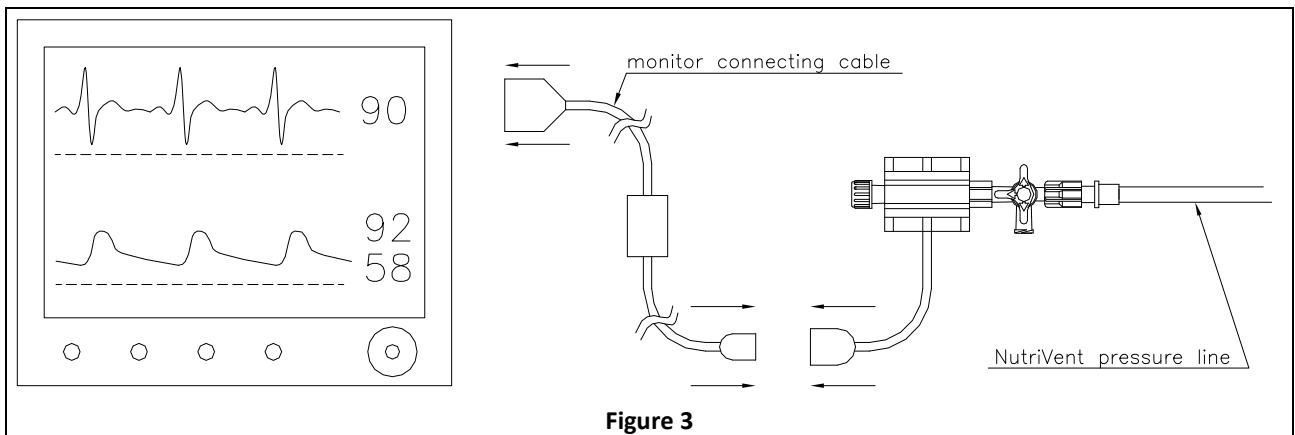


Figure 3

- 3) Put in air the pressure transducer by rotating the three-way stopcock properly and carry out the zero procedure on the monitor (Figure 4).

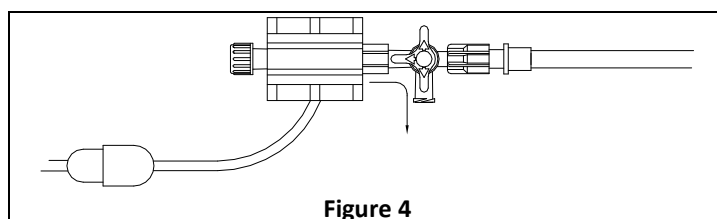
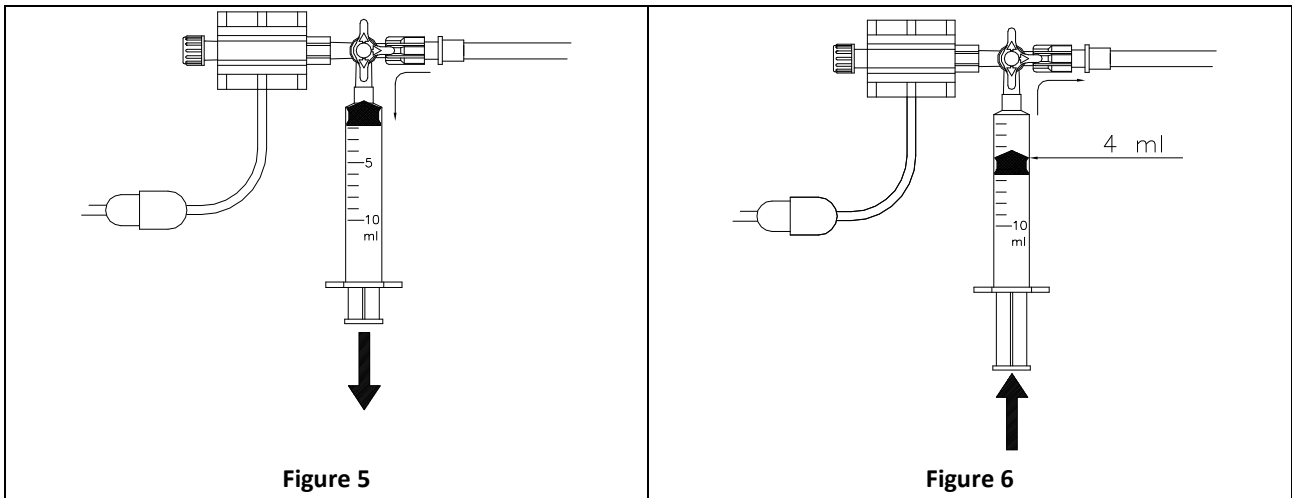


Figure 4

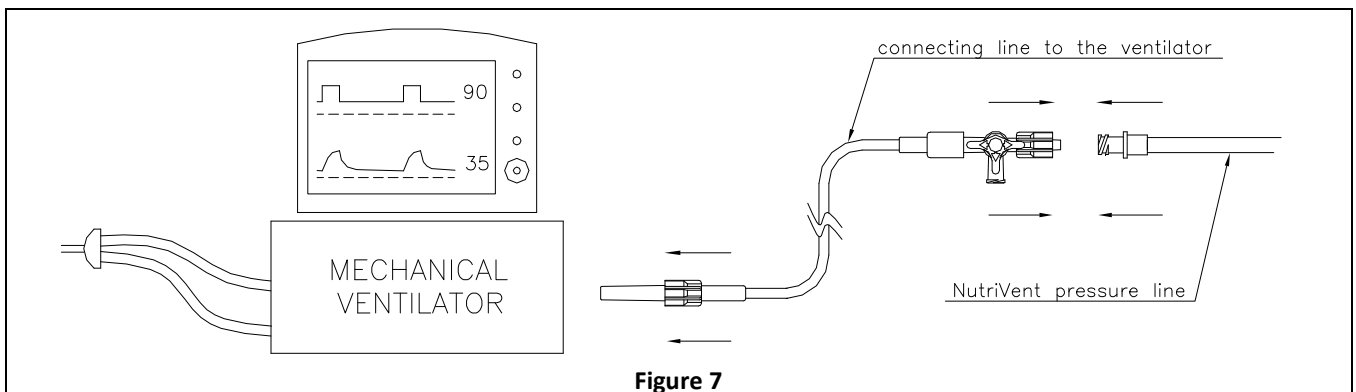
4) Through the provided syringe, suck all the air from the balloon (**Figure 5**) and then insufflate an air volume of 4 mL (**Figure 6**); at the end, close the three-way stopcock, by connecting the pressure transducer to the pressure line to measure.

⚠ For an accurate reading, the procedure at item 4) shall be repeated if more than an hour has elapsed from the last measurement.



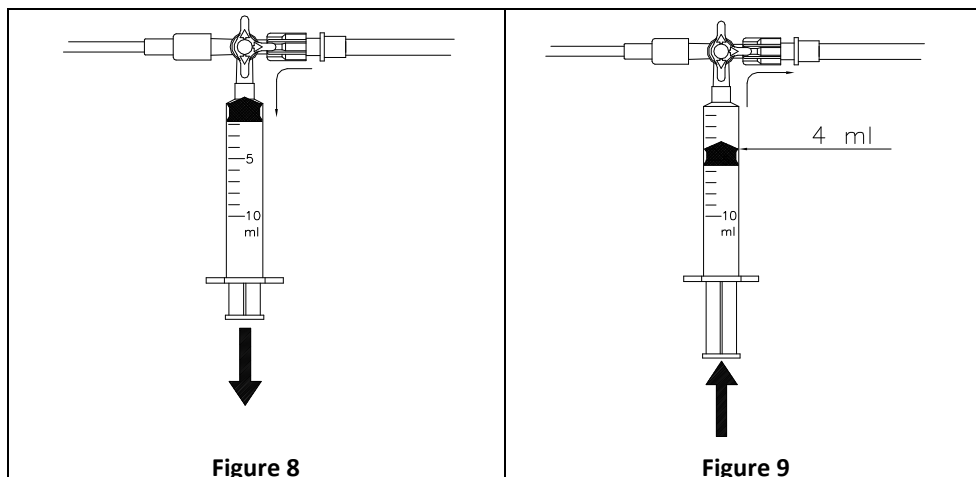
Connection to the ancillary input of the ventilator

1) Connect the pressure line you want to read (esophageal or gastric) to the ancillary input of the mechanic ventilator or through the dedicated connection line (**Figure 7**).



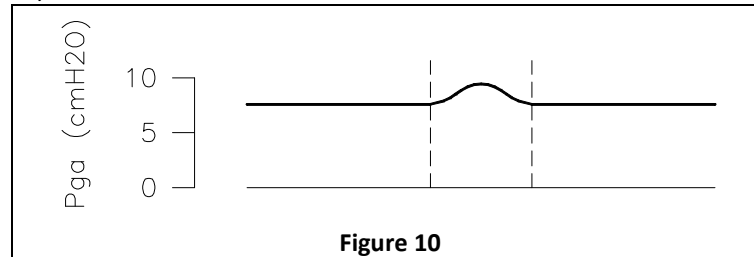
2) Through the provided syringe, suck all the air from the balloon (**Figure 8**) and then insufflate an air volume of 4 mL (**Figure 9**); at the end, close the three-way stopcock by connecting the ancillary input of the ventilator with the balloon.

⚠ For an accurate reading, the procedure of the item 2) shall be repeated if more than an hour has elapsed from the last measurement.



Verification of the correct positioning of the gastric balloon

- 1) Press the abdomen in correspondence with the epigastrium and check that there is a transitory increase of the gastric pressure (Figure 10).



Verification of the correct positioning of the esophageal balloon

- 1) In patients without spontaneous respiratory activity, the variations of esophageal and gastric pressure will always be positive in the whole respiratory cycle; on the contrary, in patients with spontaneous respiratory activity, if the diaphragm works properly, at the start of the respiratory act, the variations of gastric pressure will be positive while the esophageal ones will be negative.
 - a. In the intubated patients with spontaneous activity it is useful to carry out an occlusion test of the aerial tracts (respiratory effort with occluded aerial tracts) to verify that the variations of the esophageal pressure change accordingly to the airway pressure during an inhaling effort.
 - b. In patients subject to non invasive ventilation, the esophageal pressure will always be negative at the beginning of the inhaling act.
 - c. The NutriVent™ catheter is provided with 2 radiopaque markers placed at the end of the esophageal balloon and at the beginning of the gastric balloon, easily to be identified with a simple x-ray of the chest wall. The two markers shall be at the end of the esophagus and in the stomach.

MEASUREMENTS

The measurements read on the monitor by using the NutriVent™ catheter are expressed in millimeters of mercury: to express them in water centimeters, it is necessary to multiply the values read with a scale factor equivalent to 1.36.

For example, 12 mmHg are equivalent to $(12 \times 1,36) = 16.3 \text{ cmH}_2\text{O}$.

Measurement of the transpulmonary pressure

Mechanical ventilation

During the mechanical ventilation, for a correct measurement of the *Transpulmonary pressure* (P_L), it is necessary that the patient is well fitted for the mechanical ventilation, suitably sedated and, possibly, curarized. The ventilation mode does not matter.

After positioning the NutriVent™ catheter, carry out a pause of exhalation end followed by a pause of inhaling end. In this way, the exhaling flow as well the inhaling flow will be absent and the pressures, which will develop inside the respiratory system, will only reflect the elastic properties, those leading to the lung damage, if any. In case it would not be possible to pause (for example, with ventilators not provided with this function), it is, however, possible to use the esophageal pressure values as well as the aerial tracts ones read at the end of the exhalation and at the end of the inhaling.

The **Figure 11** provides an example of the pressure trace of the aerial tracts and of the esophageal pressure during a pause of exhalation end and inhaling end; the **Figure 12** provides a trace example without pauses.

The aerial tracts pressure of exhalation end will be directly read on the monitor or on the panel of the ventilator as the pressure developing at the exhalation end, which is usually equivalent to the PEEP set, if there is not automatic PEEP, or greater than the PEEP set on the ventilator, in case of automatic PEEP.

The aerial tract pressure of inhaling end will be read as the pressure developing during the pause (P_{aw} of plateau, **Figure 11**) or as the pressure developing at the inhaling end (P_{aw} of peak, **Figure 12**).

Similarly, the esophageal pressure will be read on the monitor or on the ventilator as the pressure developing at the exhalation end as the pressure developing at the exhalation end, while the pressure of inhaling end will be read as the pressure developing during the pause (P_{es} of plateau, **Figure 11**) or as the pressure developing at the inhaling end (P_{es} of peak, **Figure 12**).

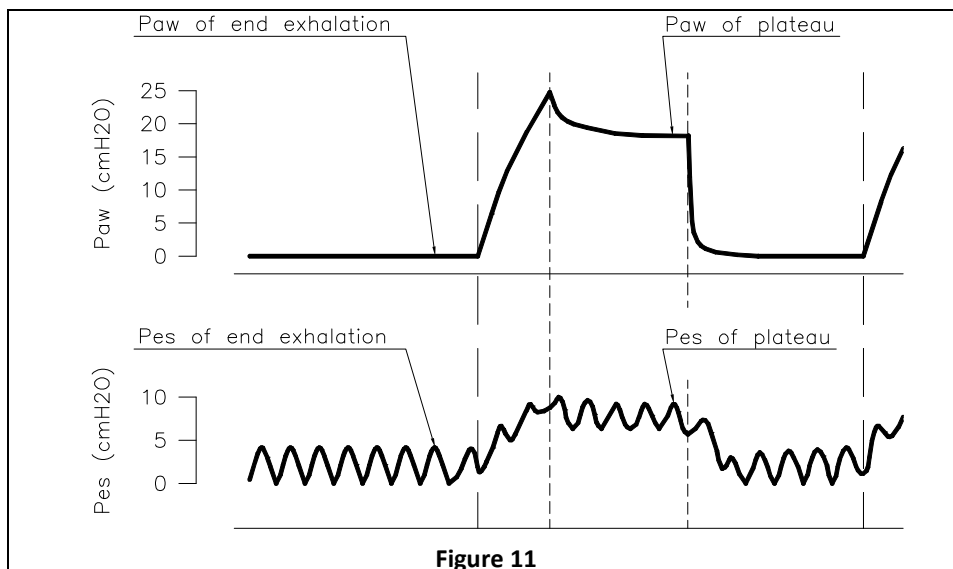


Figure 11

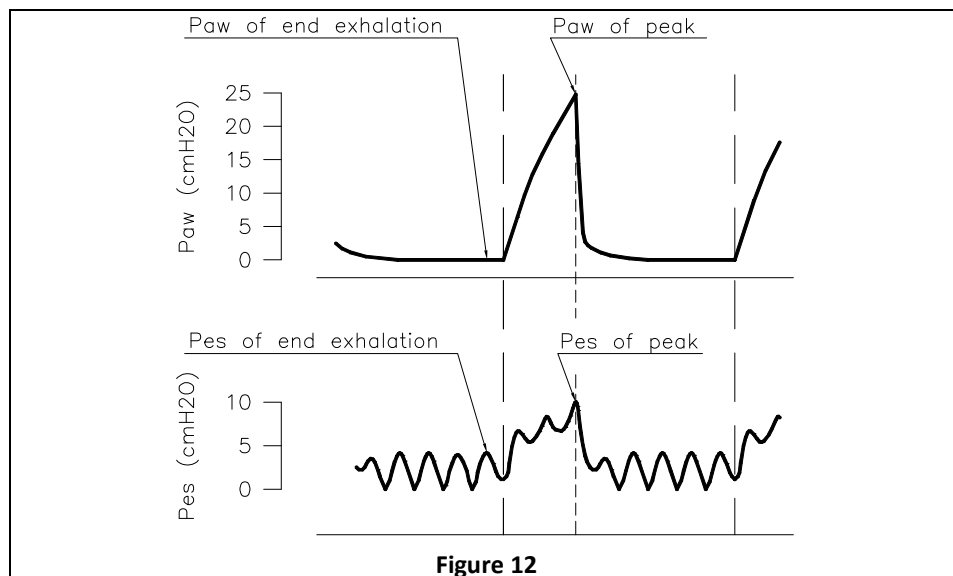


Figure 12

Legend: P_{aw} = Airway pressure; P_{es} = Esophageal pressure

Knowing the *Airway pressure* (P_{aw}) and the *Esophageal pressure* (P_{es}), calculate the variation of *Transpulmonary pressure* (ΔP_L) by the following formula:

$$\Delta P_L = (P_{aw} \text{ of inhaling end} - P_{aw} \text{ of exhalation end}) - (P_{es} \text{ of inhaling end} - P_{es} \text{ of exhalation end})$$

To obtain an accurate measurement of the *Airway pressure* and of the *Esophageal pressure* it is necessary that the pause of inhaling and exhalation end have a duration of 2-4 seconds.

⚠ In case of artefact in the trace of the esophageal pressure, for example spasms, the measurement shall be repeated.

Measurement of the compliance / elastance of the respiratory system, of the lung and of the chest wall

To obtain the measurement of the compliance / elastance, it is necessary to know the *Esophageal pressure*, the *Airway pressure* and the *Tidal volume*. The aerial tracts and esophageal pressure will be measured as in the case of the measurement of the transpulmonary pressure (chapter "Measurement of the transpulmonary pressure"). To obtain an accurate measurement of the *Airway pressure* and of the *Esophageal pressure* it is necessary that the

pause of exhalation and inhaling end has a duration of 2-4 seconds In absence of pause of exhalation and inhaling end, it is always possible the calculation of the compliance / elastance.

⚠ In case of artefact in the trace of the esophageal pressure, for example spasms, the measurement shall be repeated.

The compliance / elastance of the respiratory system, of the lung and of the chest wall will be calculated by the following formulas:

Compliance

<i>Respiratory system</i>	$C_{RS} = \frac{\text{Tidal volume}}{P_{aw} \text{ inhaling end} - P_{aw} \text{ exhalation end}}$
<i>Lung</i>	$C_L = \frac{\text{Tidal volume}}{(P_{aw} \text{ inhaling end.} - P_{aw} \text{ exhal. end.}) - (P_{es} \text{ inhal. end} - P_{es} \text{ exhal. end})}$
<i>Chest wall</i>	$C_{CW} = \frac{\text{Tidal volume}}{P_{es} \text{ Inhaling end} - P_{es} \text{ Exhalation end}}$

Elastance

<i>Respiratory system</i>	$E_{RS} = \frac{P_{aw} \text{ inhaling end} - P_{aw} \text{ exhalation end}}{\text{Tidal volume}}$
<i>Lung</i>	$E_L = \frac{(P_{aw} \text{ inhaling end.} - P_{aw} \text{ exhal. end.}) - (P_{es} \text{ inhal. end} - P_{es} \text{ exhal. end.})}{\text{Tidal volume}}$
<i>Chest wall</i>	$E_{CW} = \frac{P_{es} \text{ inhaling end} - P_{es} \text{ exhalation end}}{\text{Tidal volume}}$

Legend: P_{aw} = Airway pressure; P_{es} = Esophageal pressure.

Measurement of the inhaling effort

After placing the NutriVent™ catheter and put in reading the line of the *Esophageal pressure* on the monitor or on the ventilator, the maximum variations of the *Esophageal pressure* (ΔP_{es}) will be measured from the beginning of the inhaling to its maximum excursion.

The **Figure 13** provides the ventilation case in CPAP, while the **Figure 14** provides the case of the assisted ventilation.

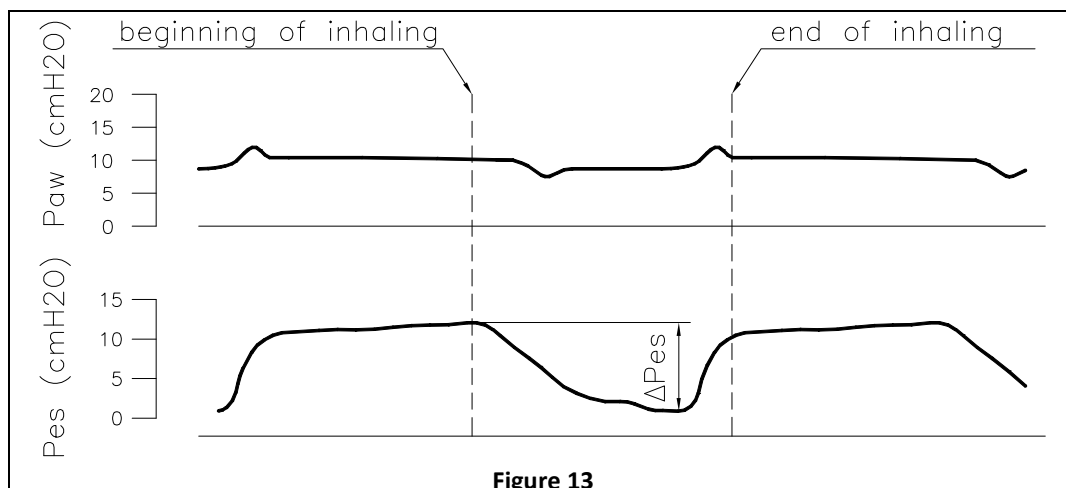


Figure 13

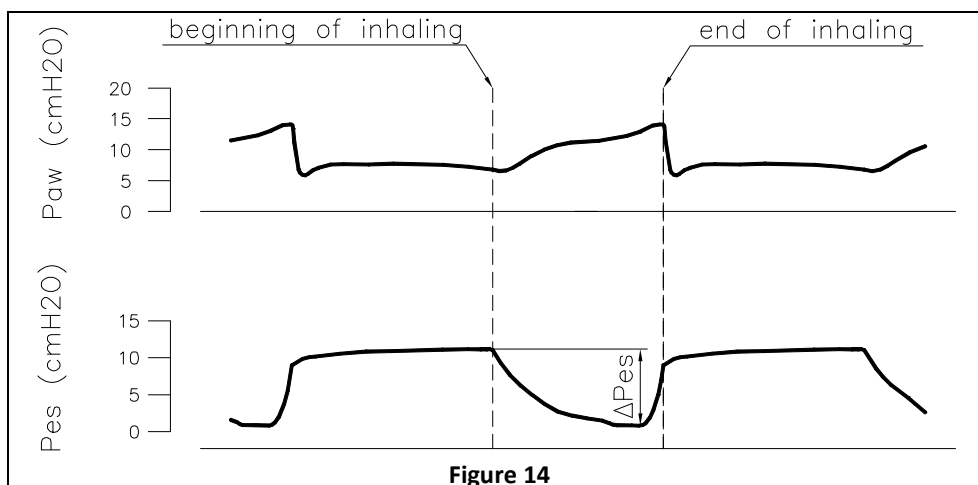


Figure 14

⚠ In case of artefact in the trace of the esophageal pressure, for example spasms, the measurement shall be repeated.

Measurement of the gastric pressure

After placing the NutriVent™ catheter and connecting the gastric pressure line to the monitor or to the ventilator:

- 1) place the patient in supine position;
- 2) read the value of Gastric pressure (P_{ga}) during the exhalation stage (Figure 15).

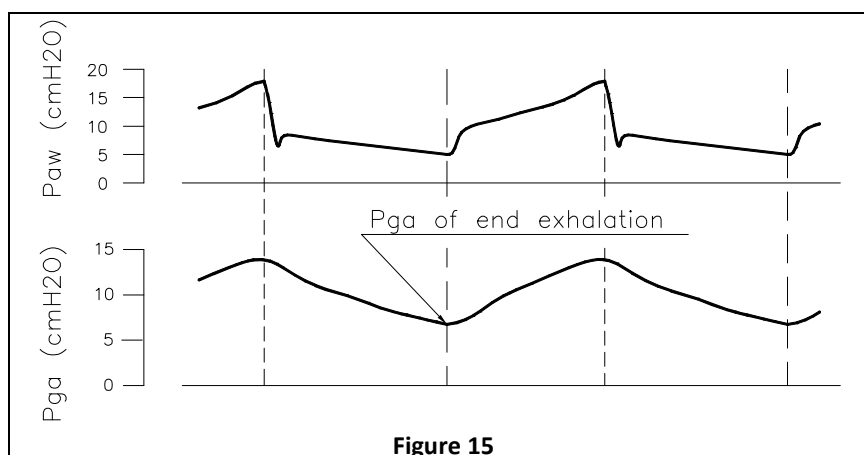


Figure 15

REFERENCE VALUES

Table 1 - Compliance

	C_{RS} [mL/cmH ₂ O]	C_L [mL/cmH ₂ O]	C_{CW} [mL/cmH ₂ O]
Healthy individuals in general anaesthesia	70-80	110-130	180-210
Individuals with ALI/ARDS	30-40	40-60	70-100
COPD individuals with respiratory failure	50-90	100-170	150-260

Legend: C_{RS} = Respiratory system compliance; C_L = Pulmonary compliance; C_{CW} = Thoracic compliance;
COPD = Chronic Obstructive Pulmonary Disease;

Table 2 - Elastance

	E_{RS} [cmH ₂ O/L]	E_L [cmH ₂ O/L]	E_{CW} [cmH ₂ O/L]
Healthy individuals in general anaesthesia	12-14	8-9	4-5
Individuals with ALI/ARDS	25-37	17-24	8-13
COPD individuals with respiratory failure	11-19	6-10	5-9

Legend: E_{RS} = Respiratory system elastance; E_L = Pulmonary elastance; E_{CW} = Thoracic elastance;
COPD = Chronic Obstructive Pulmonary Disease;

Table 3 – Abdominal pressure

	Abdominal pressure	
	[mmHg]	[cmH ₂ O]
Normality	4-7	5,4-9,5
Abdominal hypertension	≥ 12	≥ 16,3
Compartmental syndrome	≥ 20	≥ 27,2
	Associated to the appearance of a new organ failure	

BIBLIOGRAPHY

(1) Chiumello D, Carlesso E, Cadringer P, Caironi P, Valenza D, Polli F, Tallarini F, Cozzi P, Cressoni M, Colombo A, Marini JJ, Gattinoni L. "Lung Stress and Strain in Acute Respiratory Distress Syndrome" Am J Respir Crit Care Med. 2008 Aug 15; 178(4):346-55.

IMPORTANT INDICATIONS

The device allows to detect and register, in continuous, the values of the *Gastric pressure* and of the *Esophageal pressure*, but does not allow the automatic adaptation of the ventilator, operation to be strictly carried out, manually, by the physician.

WARNINGS

The reuse of the device may also result in serious worsening of the health status because of possible microbial contaminations.

DISPOSAL

The used device must be disposed of as hospital waste according to the regulations in force.

MANUFACTURER



SIDAM s.r.l.
Via Statale Sud, 169
41030 San Giacomo Roncole
MIRANDOLA (MO)

LATEX FREE

