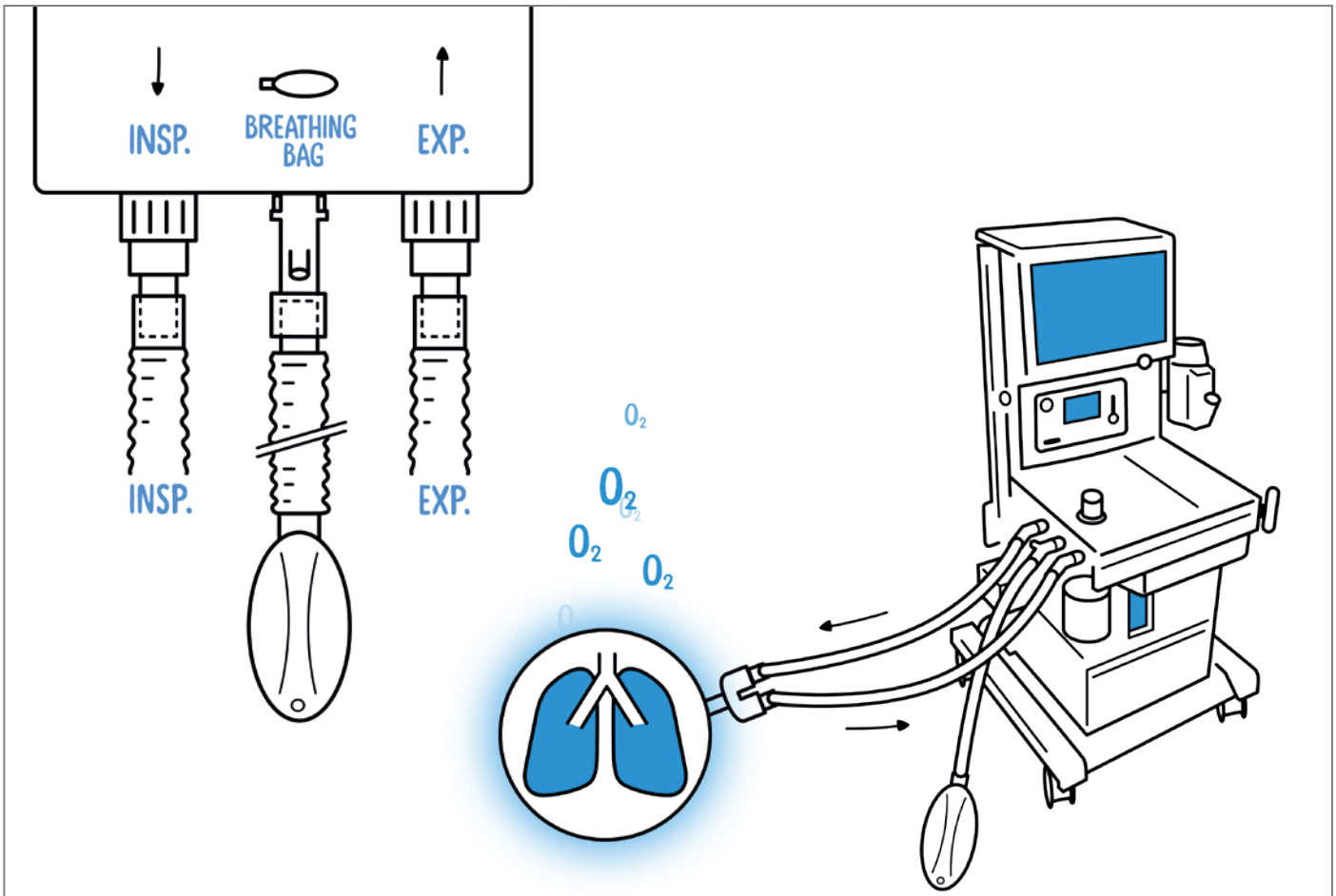


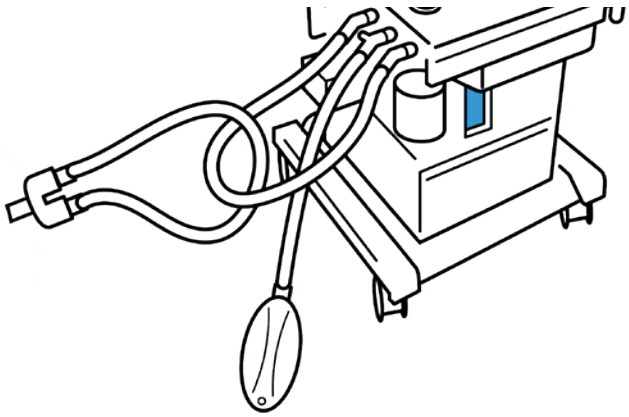
Incorrect connections of breathing hoses

A potentially fatal but avoidable problem

In recent years, an increasing number of serious cases of misconnected ventilation hoses have been reported in Germany and other countries. Even though this problem occurs rarely, it must be avoided in any case. Technical solutions as well as simple and quick control options for the anaesthesiologist are presented in the following article.

Hose misconnection and possible consequences?

Between 2013 and 2020, seven cases of falsely connected hoses with serious consequences were reported to the German Federal Institute for Drugs and Medical Devices (BfArM)[1]. In all cases the first tube was connected to both the expiratory and inspiratory ports of the anaesthesia device, and the second tube was connected to the Y-piece at both ends.



Picture 1: Hose short circuit with resulting non-ventilation

The setup resulted in a "short circuit" with no connection between the device and the patient and thus without any ventilation. As a result, one patient died and two others suffered severe hypoxic brain damage. Another case of serious hose misconnection has been reported in Poland, as well as a fatal incident in France in 2019.[2]

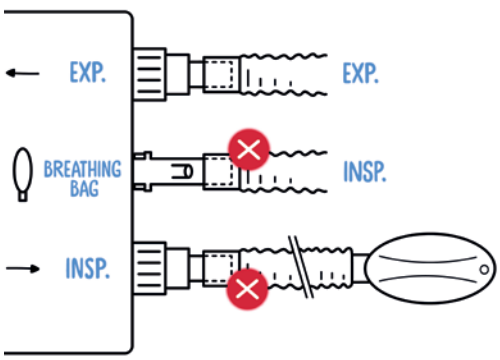
Why can hose misconnection occur?

The technical norm for the design of the three ports for the inspiratory hose, the expiratory hose and the breathing bag hose are constructed identical (ISO 80601-2-13). Up to now, the accessories could be universally plugged onto all three ports because of the same dimensions.

Thus, there are three possibilities of misconnection, which have different effects, but have in common that the patient is not ventilated adequately.

1. Interchange of inspiration hose and breathing bag hose.

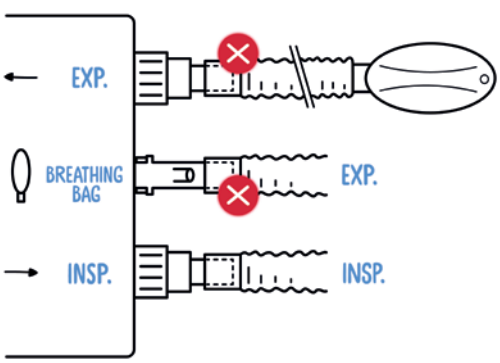
In this case, the patient is connected to the expiratory port and the port for the breathing bag hose. This means that no fresh gas is supplied to the patient, so oxygen supply and ventilation of the patient is not possible in this case. Furthermore, there is a risk that gas will be sucked out of the patient's lungs during mechanical ventilation and ultimately a negative pressure will be applied.



Pictures 2: Interchange of inspiration hose and breathing bag hose.

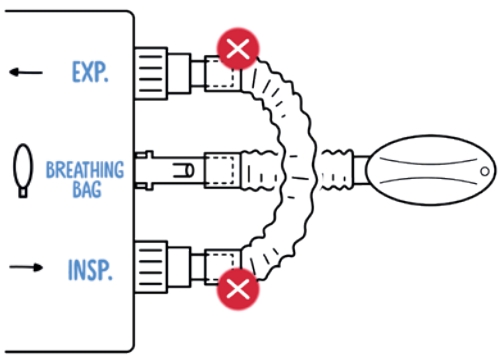
2. Interchange of expiration hose and breathing bag hose.

The patient is connected to the inspiratory port and the port for the breathing bag hose. In this case, oxygen supply to and ventilation of the patient is also not possible. In addition, excessive pressure in the patient's lungs may result in barotrauma and pneumothorax.[2]



Pictures 3: Interchange of expiration hose and breathing bag hose.

3. Short-circuit of inspiratory and expiratory port.
In this case, the patient is not connected to the anaesthesia machine at all. Oxygen supply and ventilation of the patient is also not possible in this case. This error pattern can only occur if the hoses are not permanently connected to the Y-piece or to the water traps.



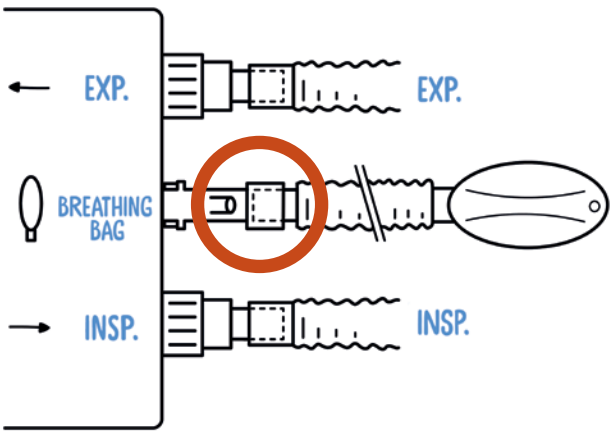
Picture 4: Short-circuit of inspiratory and expiratory port.

Recognising and preventing hose misconnection and reacting adequately

The retrospective evaluation of the critical incidents by the German Federal Institute for Drugs and Medical Devices (BfArM) and the German Society for Anaesthesia and Intensive Care Medicine (DGAI) revealed potential for improvement in three essential areas: a) the technical conditions, b) the functional testing of the equipment and c) the user's crisis management.[1]

Technical conditions. The fact that the connectors for the ventilation hoses and the breathing bag hose are identical bears the risk for different hose misconnections. But there are different technical approaches to mitigate this risk.

New standard ISO 80601-2-13. An amendment to the ISO standard regarding the connection of the breathing bag hose whas been subject to discussion in recent years. The German BfArM reacted to the incidents in a special meeting in 2019 and introduced additional proposed amendments to the standard regarding the hose systems. The new revision of ISO 80601-2-13 is expected to be adopted in the second half of 2021 and is intended to contribute to design safety by changing the diameter of bag elbow, which is the connector for the breathing bag hose at the device side ("gender conversion of the connector"). It will then no longer be possible to plug inspiratory or expiratory hoses onto this port. Conversely, it is then also no longer possible to plug the breathing bag hose onto one of the other two ports.



Picture 5: Changing the diameter of the bag elbow – the port to connect the breathing bag hose - prevents accidental connection of inspiration or expiration hose

The conversion is possible with all current Dräger devices by changing the port for the breathing bag hose.

The upcoming revision of ISO 80601-2-13 will also stipulate that only ventilation hose systems that prevent short-circuiting of the inspiratory and expiratory ports by design or make it obvious may be used in conjunction with anesthesia equipment. In the case of single-use hose systems, for example, inseparable connections of the hoses with the Y-piece and, if applicable, the water traps are one way of preventing short circuits between the inspiratory and expiratory ports.

Functional testing of the equipment

Step 1: Device check according to the instructions for use. An adequate functional check of the device can detect a hose exchange at an early stage. In many countries the obligatory device check according to the instructions for use is mandatory every 24h and is performed as a semi-automatic self-test for most devices

(important: please mind and adhere to your national regulations in this context). Anesthesia devices from Dräger offer numerous simplifications here, e.g., via the scope of the tests, which are performed automatically, simplified preparations for the device, some of which are guided on the device display, and the time-controlled start of the self-test (Auto-On) in the morning before the start of surgery. However, by far not all anesthesia machines detect the short-circuit of inspiratory and expiratory port during the self-test; especially with older machines, this is a rarely encountered exception. The Dräger anesthesia machines Zeus IE, Perseus A500 and the Atlan family are able to detect a hose short circuit during the self-test and the leakage test. However, even though such technical facilitations help in checking the equipment regularly, they cannot provide complete safety. Since this functional test is only mandatory every 24 hours, it typically does not intervene in the detection of faulty connections made during daytime operation.

Step 2: AWS-QUICKcheck. For years, the German Society for Anaesthesiology and Intensive Care (DGAI) has urgently recommended that before connecting a patient to an anesthesia machine, the attending anesthesiologist must perform a so-called QUICKcheck of the anaesthesia workstation (AWS), which is not to be delegated. This involves checking the gas flow before connecting the patient. After connecting the patient, the O_2 content of the ventilation gas is checked via the FiO_2 measurement. Finally, capnometry is used to check whether the lungs are ventilated. Even though the AWS-QUICKcheck was issued by the German Society for Anaesthesiology and Intensive Care (DGAI), it was also published in English lanugage[3] (Link) The QUICKcheck is essential for every patient connection and should be seen as complementary to the thorough daily functional check.

"AWS-QUICKcheck of the anaesthesia machine;
10 seconds for patient safety; always!"[3]

In this context, it should be noted that even after conversion of the bag elbow or when using accessories in line with the upcoming revision of ISO 80601-2-13, the AWS-QUICKcheck should still be carried out before each connection of a patient to an anaesthesia machine, as this can also be used to identify other potential cases of error at an early stage and reduce patient risks. Please mind and adhere to applicable recommendations of your national societies in this context.

In detail, the AWS-QUICKcheck specifies the following procedure[3]:

Before connecting the patient to the anesthesia machine

Here, the gas flow functionality of the breathing system is tested by means of the so-called PaF test (**P**ressure and **F**low). For this purpose, the following is done on the device

a. the Man/Spont mode is selected,
b. the APL valve is set to 30mbar,
c. the opening on the Y-piece of the hose system is occluded and
d. the breathing bag is taken in the hand and filled via the O_2 flush

Result:
- During manual compression, the breathing bag may not empty (**P**ressure)
- If the patient-side connection of the Y-piece is opened again, a gas flow must be clearly noticeable (**F**low)

After connecting the patient to the anesthesia machine

- Deliver a few manual/assisted breaths before starting mechanical ventilation.
- Check the inspiratory oxygen concentration to ensure that an adequate FiO_2 is being delivered (and not just air or even nitrous oxide).
- Check the plausibility of the measured capnometry values to ensure that the lungs are being ventilated.

CAVE:
- During induction of anesthesia, the above steps are performed with the mask on the face of the patient and a fresh gas flow of >2l.
- If mechanical ventilation is continued in the OR after transfer from the induction room, the steps are performed directly after connection of the endotracheal tube (ET) to the device.

User's crisis management

The German Society for Anaesthesia and Intensive Care Medicine (DGAI) recommends immediately ventilating the patient with a separate emergency hand resuscitator, i.e., bypassing the anesthesia machine's tubing system, in all cases of ventilation problems and then to systematically search for the cause of the ventilation issue. Rapid hand ventilation with an emergency hand resuscitator could possibly have prevented the hypoxic damage in the above mentioned cases.[1] Therefore, always ensure that an emergency hand resuscitator is readily available.[3]

If abnormal findings are encountered during ventilation, the patient is to be disconnected from the device again. Continue to ventilate with the emergency hand resuscitator without filter and initiate a systematic search for the cause of the issue.[3]

A systematic search for issues with ventilation during operation aims to detect both stenoses and leakages.

• **Stenoses** are characterized by unusually high ventilation pressures. If ventilation is easy with the emergency hand resuscitator, the stenosis is on the side of the filter, hose system or device. If ventilation is difficult, the issue is on the patient's side. With the aid of a suction catheter, the cause can be differentiated more closely on the patient side.[3]

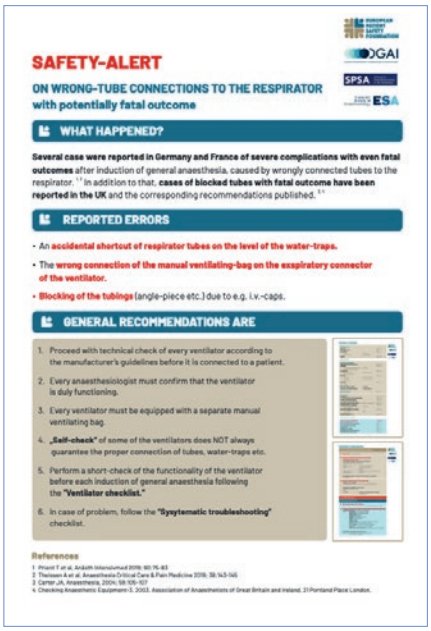
• **Leakages** are indicated by insufficient pressure build-up. After setting a fresh gas flow to 12-15l/min, the expiratory tidal volume is checked. If the tidal volume is sufficient, a systematic leakage search is performed. If the expiratory tidal volume is not sufficient, ventilation is continued manually with an emergency hand resuscitator without filter and further clarification is performed to differentiate again whether the leakage is in the area of the airway (tube/cuff leaking?) or on the side of the tubes and equipment.[3]

In order to be able to react adequately in the event of a crisis, the German Federal Institute for Drugs and Medical Devices (BfArM) also recommends that stenosis and leakage incidents be addressed in the medical curriculum and in simulation training.[3]

Also on a European level, the European Patient Safety Foundation (EUPSF) together with the European Society of Anaesthesiology (ESA), the German Society for Anaesthesiology and Intensive Care (DGAI) and the Foundation for Patient Safety in Anaesthesia (SPSA) have published a recommendation on how to check the devices and act in case of doubt to prevent fatal consequences of tubing mix-ups.

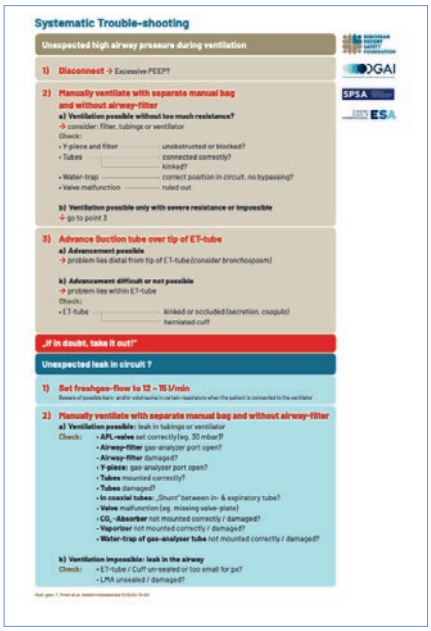
Please see the EUPSF Website:
https://www.eupsf.org/safety-alert-wrong-tube-connections

Three documents in a check-list fashion are being offered for download to help tackling the issue of hose misconnections:



Safety-Alert (Link)

Ventilator - Checklist (Link)



Systematic Trouble-Shooting (Link)

CONCLUSION

Although the incidence of hose misconnection is quite low, these few cases can and must be prevented because of the potentially serious consequences associated with them. The use of the safest possible accessories (e.g., a replaced bag elbow at the anesthesia device and firmly connected hose systems according to the upcoming revision of the ISO 80601-2-13 standard), a simple AWS-QUICKcheck before each connection of a patient to an anesthesia machine, and routine management of critical situations are together critical to patient safety in anesthesia.

For more in-depth information on preventing critical incidents in the OR, also read our article, "All Too Complex? Preventing and successfully managing critical incidents in anesthesia" (Link).

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3. *Prien T, Bürkle H, Czaplik M, Hölzl M, Hönemann C, Grensemann J et al. Funktionsprüfung des Narkosegerätes zur Gewährleistung der Patientensicherheit. Anästh Intensivmed (2019), 60, 75-83 doi:10.19224/ai2019.075*

DMC-100792 | 21.10-3