Technology Insights

Human error in anaesthesia: whose fault is it anyway?

Efforts to reduce human error during general anaesthesia poses major requirements to anaesthesia workstations. Dräger works closely with clinicians and nursing staff around the world to understand the precise needs and requirements for supporting measures in the OR. Below we describe the latest technologies in our anaesthesia workstations supporting the reduction of medical error during anaesthesia.

Technology for Life

INTRODUCTION:

The anaesthesia workplace is a complex, demanding and often stressful environment. For many anaesthesiologists, the challenges from the workplace can be overwhelming: increasingly complex medical cases, close coordination with the surgical team and frequent distractions are accompanied by production like conditions, such as time/cost pressure, sleep deprivation caused by shift systems and no time to keep up with the latest guidelines and evidence. This situation is likely to impact clinical decision making negatively, potentially promoting a medical error incident. Medical error in the perioperative period frequently has a fatal impact on patient outcomes and high consequential costs. In our clinical whitepaper we elaborate on medical error and decision making in perioperative anaesthesia care and analyse the potential reasons for this. Please click here to read more.

Dräger strives to design anaesthesia workplaces which support care teams in making fast and informed decisions in order to reduce the risk of medical error and to be quicker and better in managing complications and/or challenging patients/procedures. To achieve this, from our perspective, three main areas of an anaesthesia workstation need to be optimised to achieve the above goal:

KEEP IT SIMPLE AND SAFE – MITIGATING THE RISK FOR ERROR AT STARTUP

Confident use of the anaesthesia device comes with the simplicity of its design. Do I spot the right information on the screen right at the moment when I need it? Can I handle the device securely under extreme time pressure? Is the device checked and made ready for the next patient easily and quickly? Technology needs to make it easy for users – even if the complexity of the device is large. Clearly arranged graphical user interfaces and intelligent support, e.g. for the choice of the right ventilation settings, support the confident use of the anaesthesia workstation even under extreme stress. But frankly, all manufacturers claim this for their devices. It is very subjective whether the user interface allows for confident use. However, here are some examples of functionalities we think will make your life easier and will allow for increased patient safety.

Guided self-test preparation and automatic wake-up for self-test.

One hazard concerning patients safety in the OR, identified by Bohnet-Jenschko et al., was the insufficient preparation of medical devices, esp. the anaesthesia device, as it was not carried out according to the specification of the manufacturer.[1] Frankly, preparing the self-test and carrying it out is often cumbersome, eats into valuable time and in the end the device might not even be fully functional. Dräger has gone a different way in addressing this everyday issue with the Perseus® A500. Independent from what test you need to run, a leakage test for the next patient or a complete system test for the next day, the Perseus provides detailed, easy to follow “check-list”-like instructions on the screen on what to do in order to run the test. Furthermore, the Perseus® A500 automatically displays the tests which need to be performed on the stand-by screen. This way, it is easy to make sure the manufacturer’s specifications are followed in a streamlined and effective way.

Furthermore, Perseus saves time by offering an automated, time-scheduled system test. Once prepared for the test, the user can select a time at which the device is required to

have completed the system test. The device will then wake up from sleep mode automatically and run the test so that it is ready for use by the targeted time.

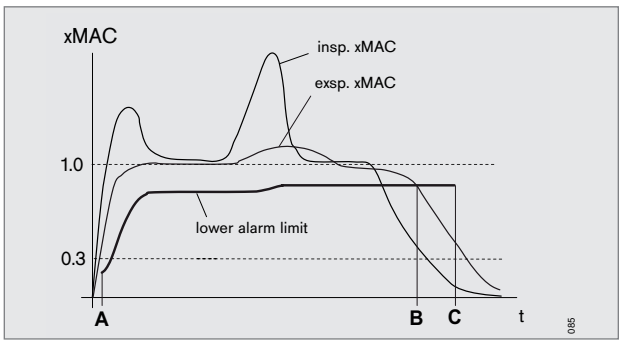
Start-Settings for ventilation and fresh gas.
The anaesthesia machines in the Primus®- and Zeus® families and the Perseus® A500 – can start ventilation with pre-set values for the ventilation parameters, such as tidal volume and breathing frequency based on ideal bodyweight, if the patient's height or ideal body weight are entered. The corresponding ventilation settings are calculated from these data. In standard configuration, these settings can be pre-defined according to department or hospital protocols. This is especially important and necessary in regards of protective ventilation strategies, since the recommendations for low tidal volumes per kg of body weight always refer to ideal body weight. It is also possible to pre-set the flow and concentration of fresh gas which the device delivers at the start of the operation. This can support the recommended FiO_2 dosage. Also under stress, this helps to ensure that the right settings are chosen for the individual patient based upon departmental standards (SOPs) and clinical evidence – if default settings have been accordingly set.

xMAC Calculation.
In order to ensure sufficient delivery of volatile anaesthetic agents, the dosage needs to be adapted to the age of the patient. The xMAC value takes this factor into account. Apart from checking the expiratory volatile anaesthetic concentration, Dräger anaesthesia machines with integrated patient gas monitoring display the age-adapted xMAC to provide important additional information for dosing volatile anaesthetic agents. By these means, the user is well informed of the xMAC value currently provided to the patient. However, it is important to enter the patient's age into the system to ensure the correct calculations.

SMART ALARM FUNCTIONALITIES

As already elaborated on in our clinical whitepaper, alarm fatigue is not just a topic for the intensive care unit. Also anaesthesiologists are frequently bombarded with a high number of alarms, potentially causing the finger to "automatically" push the alarm silence button without having consciously perceived the cause of the alarm.

MAClow Alarm.
Frequent distractions and critical phases can impair situational awareness. Thus, a creeping or even sudden decrease in MAC value may remain unattended. In order to avoid inadvertently low MAC values, which put the patient at risk of awareness episodes, Dräger Perseus® A500 and Primus®/Primus® IE anaesthesia machines offer the MAClow alarm. This is an alarm limit which is automatically activated and adjusted to clearly bring the fact to the user's attention that the MAC value has fallen below the targeted value so that the user can act in a timely fashion.



Operating principle behind the "Low MAC" alarm

Deactivate CBM.
This function supports to avoid a potentially fatal mistake in cardiac surgery. When the patient is on-pump during coronary artery bypass surgery, the Dräger Perseus® A500 offers an HLM mode which switches off relevant alarms, such as CO_2 and minute volume alarms in order to prevent useless alarms during this procedure. However, when taking the patient off-pump and regular ventilation starts again, the HLM-mode needs to be turned off in order to reactivate the aforementioned, vital alarms. If this is forgotten, the anaesthesiologist runs the risk of missing dangerous increases of CO_2 or decreases in minute volume. When in HLM mode, the Perseus® A500 continues to measure the parameters even when the mode turns off the alarms. If the system realises, e.g. CO_2 or minute ventilation values indicating that regular ventilation has been resumed, it will alarm the user to deactivate the HLM-mode in order to get alarmed again if vital parameters get out of range.

No CO_2 detected.
Although auscultation after intubation minimises the risk of unnoticed oesophageal malpositioning of the tube, it does not resolve the risk completely. Also other reasons may lead to tube malpositioning and thus to ineffective ventilation. Especially in critical phases, like the induction phase, this might remain unnoticed and can thus lead to hypoxic events. Dräger Perseus® A500 anaesthesia machines offer an alarm upon failure to measure CO_2 one minute after ventilation is started thus counteracting patient harm in phases of impaired situational awareness.

Auto-Wakeup for CO_2 Alarm.
This alarm is a smart aid in a different situation which could also potentially result in patient harm. In some cases, the CO_2 alarm might be turned off for various reasons. Having forgotten to turn it back on, might result in the user relying on an alarm that was turned off, thus possibly missing an inadvertent increase or decrease in CO_2. Once the Dräger anaesthesia machine measures CO_2, it will automatically turn on the CO_2 alarm again so that the user receives a warning once the measured CO_2 gets out of range.

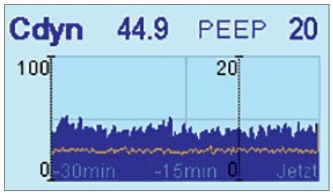
Autoset for alarm limits.
There are only a few things more annoying than unnecessary alarms. One example is recurring alarms for parameters the anaesthesiologist knows are out of range at an acceptable level and maybe even for a good reason. In order to reduce the count of undesired alarms, Dräger anaesthesia machines* will propose changes to the affected parameters giving the user the opportunity for a quick and easy adaptation of the alarm ranges according to the current situation – an active measure against alarm fatigue.

SMART VISUALIZATIONS

Based on analysis of device data and smart algorithms, our technology offers visualisations, making complex data faster and easier to understand. This can enhance the cognition of potentially dangerous situations and improve decisions to manage them, especially in situations of stress. Some functionalities even offer the user to take over routine tasks, so as to free up cognitive capacities.

Trended Graphs help observe slow but steady changes.
Individual data of certain parameters often do not provide sufficient information for judging if the patient condition changes for the good or the bad. If data are observed over time, this sequence of data provides the insight needed. As it is close to impossible to observe and remember all the data over time, a trended visualisation of data provides this overview in a quick to understand way. Dräger anaesthesia devices provide various trended graphs to improve informed decision making*. In the following, we list some of the trend graphs we offer.

– **Compliance Trend*.** Lung compliance is an important parameter to keep track of during general anaesthesia ventilation as it provides substantial information on the status of the lung. But it is also a very dynamic parameter so that individual values are of limited benefit. Looking at a trended compliance curve can provide much better insights into the lungs and the current ventilation settings as the development of the compliance over time can indicate e.g. the development of atelectasis which the anaesthesiologist might want to counteract. Thus, this display can play a substantial role in avoiding lung injury and applying a protective ventilation strategy.



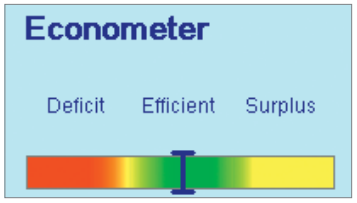
D-14691-2017
Patient compliance combined with PEEP (e.g. Primus / Primus IE – optional)

– **O_2-Uptake Trend*.** Calculated from the difference between inspiratory and expiratory oxygen concentrations and combined with the minute volume, Dräger anaesthesia devices can calculate the patient's oxygen uptake. But as individual data would be of limited value, they can be displayed as a trended graph to provide comparison and to help better identify changes.

– **MV*CO_2 Trend*.** This trend combines the measured expiratory CO_2 with the minute volume to provide a time based indication of emitted CO_2 and thus a way to track CO_2 production.

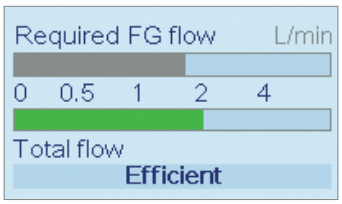
The breathing bag in Dräger anaesthesia machines.
It may sound simplistic, but indeed it may be the simplest visualisation of all: The breathing bag indicates, if the set fresh gas flow is sufficient, or not. Due to the position of the breathing bag within the breathing system, the breathing bag always reflects the gas in the system. If there is a surplus of fresh gas, the breathing bag will be very well filled or even distended. In the presence of a fresh gas deficiency, the bag will become empty. So even if you don't look at the screen, you will receive an indication whether your set fresh gas flow is sufficient, or too high or low.

Econometer/Low-Flow Wizard*.



D-826-2016
Econometer Dräger Perseus® A500

Applying low-flow anaesthesia can also play a role in protecting the patient's lungs as the ventilation gas is effectively warmed and humidified. We have elaborated on this in our corresponding clinical whitepaper. However, the beneficial effects are accompanied by a reduction of the anaesthesia machines response times to manual changes in gas concentrations. In addition, vapor and oxygen settings need to be adapted. Many anaesthesiologists do not feel comfortable with this and consequently abstain from using this beneficial technique for safety considerations as they fear that they might miss the development of hypoxic gas mixtures or insufficient volatile agent delivery.



D-828-2016
Econometer Trend (optinal)

The Dräger Econometer and the low-flow Wizard are tools which monitor the fresh-gas flow and visually indicate if the flow becomes insufficient. The tools also indicate if the fresh-gas flow is higher than required, helping the user achieve low and safe fresh-gas flows. In order to do this, the tools analyse data like patient uptake, breathing system leakage and the volume of CO_2 absorbed by the soda lime, hence comparing the sum of these values with the actual fresh-gas flow.

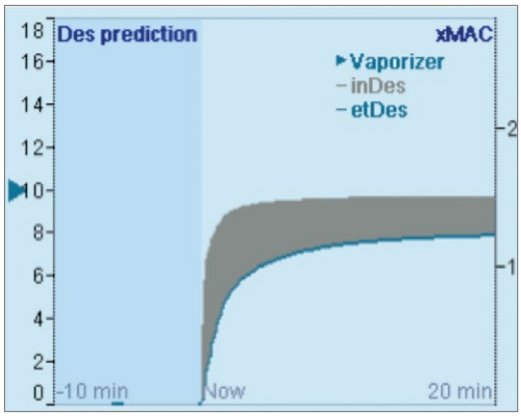
Perseus Predictive functions for anaesthetic agent and O_2.
The lower the fresh gas flow during general anaesthesia ventilation, the longer it takes until changes made to the fresh gas composition (e.g. FiO_2) or the volatile anaesthetic agent concentration settings actually arrive to the patient. This is called time constant. For anaesthesiologists, it

*Not available in Dräger anaesthesia machines of the Fabius® family.

is frequently hard to estimate the time constant, which in turn forces them to run higher flows. This way changes in O_2 or anaesthetic agent dosage get effective sooner and thus become more predictable for the user. However, this approach counteracts the beneficial effects of low fresh gas flows, such as warming and humidification of ventilation gas and significant gas savings.

In order to make the time constant more transparent, the Perseus® A500 offers intelligent predictive functions for volatile agents and oxygen when used in conjunction with the Vapor 3000 and D-Vapor 3000 anaesthetic vapourisers.

Dräger VaporView and O_2 Prediction are advanced software tools visualising a forecast of the course of anaesthetic gas and oxygen concentrations over 20 minutes and a trend of the past 10 minutes. These tools provide an easy-to-understand, graphical visualisation on how the concentration of the above mentioned gases will develop over the 20 minutes providing the user with ample time to react to undesired changes in concentration, or an indication of what effect a recently made change will have. The basis for these tools are calculations based on physiological and technological models and the ability of the device to read the volatile anaesthetic concentration set on the vapourizer (only available in Perseus® in conjunction with the Vapor 3000 / D-Vapor 3000).



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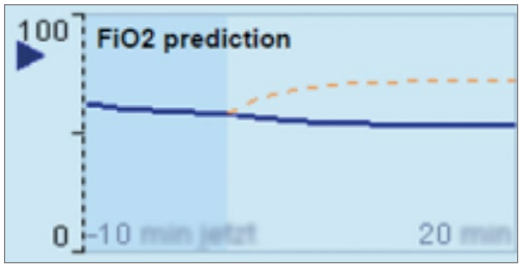
Vapor View for Dräger Perseus® A500 (option)



D-377-201

FiO_2 Prediction for Dräger Perseus® A500 (option)

SmartPilot® View – visualisation of drug effects.
Keeping the dose of anaesthetic drugs as low as possible in order to minimise the risk for adverse effects but on the other hand as high as necessary to maintain an adequate level of anaesthetia, can be challenging as interaction between hypnotics and opioid analgesics is significant. SmartPilot® View is a software that calculates and visualizes the pharmacokinetics and pharmacodynamics of the anaesthetic agents administered, offering an additional information base for assessing the level of anaesthesia.

With respect to pharmacokinetics, the effect concentrations of common opioid analgesics and volatile anaesthetics are calculated, along with those of propofol and various muscle relaxants. The machine displays the current effect concentration and a 20-minute prediction of the effect concentration for each medication. Changes in the dosage trigger recalculation.

The pharmacodynamic display shows the combined effect of propofol / volatile anaesthetics and the opioid analgesics (interaction). The 2-D display visualises the depth of anaesthesia and enables rapid recognition of the combined effect and facilitates titration of the medication for each patient.

D-19710-2015

Dräger SmartPilot® View

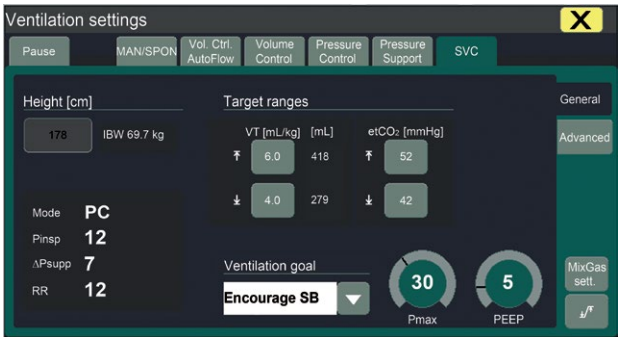
Both views together provide a comprehensive overview of the status of the patient contributing to an individualisation of anaesthetic drug titration. Even under stress or with frequent distractions, this information is available at a glance. Also hand overs for breaks or shift changes are facilitated as the “new” anaesthesiologist receives the history of drug dosing as well as the predicted future at a glance.

SmartPilot® View can be combined with products from the Primus®- and Zeus® families and with the Perseus® A500. Furthermore, SmartPilot® View is a software option for the Zeus® IE anaesthesia systems as an application in the cockpit.

Smart Ventilation Control (SVC).
Applying protective ventilation strategies consequently can absorb a significant portion of the users’ attention, especially in critical phases such as early intraoperative spontaneous breathing. Thus, distractions may lead to inattentiveness and may leave the patient exposed to a higher ventilation-associated risk.

Smart Ventilation Control is the first assistance system for ventilation in the OR which supports users during the entire procedure, from intubation all the way to extubation.

In contrast to conventional ventilation modes, users can directly set the therapeutic objective of ventilation. In this context, the objective of ventilation refers to the question as to whether the patient should receive fully controlled ventilation, or whether spontaneous breathing should be permitted or forced. Within the boundaries set by the user, SVC adjusts ventilation parameters automatically to achieve the selected ventilation objective.



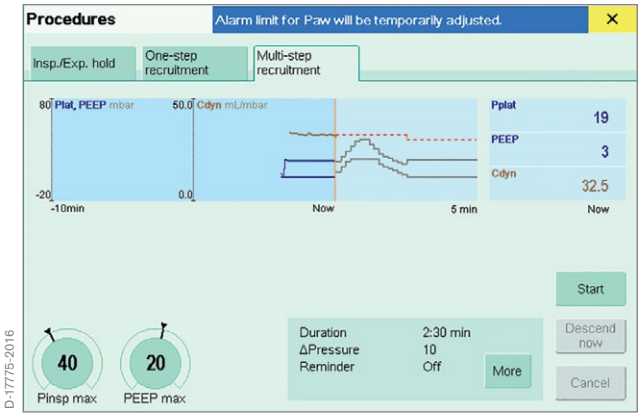
Dräger Smart Ventilation Control (SVC)

Upon start of the function, the system suggests target ranges for tidal volume and end tidal CO_2 adapted to each individual patient giving the user the option for adjustment. SVC automatically adapts the relevant ventilation parameters continuously to keep tidal volume and end tidal CO_2 always within the target ranges. This ensures a patient-tailored ventilation while simultaneously ensuring a protective ventilation application. SVC was developed in co-operation with clinicians to simplify the application of protective ventilation regimes and to promote spontaneous breathing as early as possible and with the largest possible volume. SVC can provide classical mandatory ventilation as well as support for the smooth transition to spontaneous breathing. Switching to different ventilation goals is possible anytime with a single interaction. For example, if SVC is set to target, the transfer to spontaneous breathing, it reduces mandatory ventilation as soon as possible and may also gradually reduce Pressure Support to allow the patient to breathe spontaneously. Instead of controlling various ventilation modes with a number of different parameters (Pinsp, frequency, I:E...), users can directly determine the desired ventilation objective (e.g. „controlled“ or „encourage spontaneous breathing“). This goal-oriented setting greatly reduces the number of operating steps required, and at the same time ensures the maintenance of adequate tidal volumes and a stable level for end-tidal CO_2. This aids the provision of high quality ventilation and helps reduce the cognitive workload. SVC is available with the Dräger Zeus IE anaesthesia machine.

Recruitment Manoeuvres.

Recruitment Maneuvers are discussed as an intergral component of a protective ventilation strategy. We have shed light on some pros and cons in our clinical whitepaper on this topic.

In complex cases where the cognitive capacities of the anaesthesia care team are run at limits, these manual procedures eat into valuable time and might not be performed in a protective fashion as it should be. The Dräger Perseus® A500 offers additional procedures, which allow for automated recruitment manoeuvres during normal ventilation without the need for manual adjustments of the required settings. The user just needs to set the desired pressure level(s) and time, after which the manoeuvre can be started by the touch of a button. After the manoeuvre has been conducted, the device automatically switches back to the previously set ventilation. This ensures that the preset pressure(s) and time(s) are kept reliably and that, following the manoeuvre, the desired PEEP will be maintained.



Perseus® A500 – multi-step recruitment (optional)

This applies specifically to multi-step manoeuvres. The idea behind this type of manoeuvre is to carry out the alveolar recruitment not only effectively but also as gently as possible with respect to the lung and haemodynamics. In order to do so, inspiratory pressure and PEEP are ideally increased step-by-step while maintaining a constant driving pressure. The maximum inspiratory pressure (alveolar opening pressure) is maintained for a desired amount of time, after which both, inspiratory pressure and PEEP, are gradually decreased. Each stage is maintained for a user-defined time/number of breaths. The Perseus® A500 is capable of automating the manual set-up effort for these kinds of manoeuvres, which can take up to more than 5 minutes.

The recruitment manoeuvre can be adjusted to the needs to individual patients intuitively with just a few settings. The following two settings are the main parameters:

– Maximum inspiratory pressure
– Maximum PEEP

If so desired, further settings can be made, such as for driving pressure, number of mandatory breaths per pressure stage, and number of mandatory breaths while in the maximum pressure stage. While monitoring the manoeuvre, should the user determine that the objective of the recruitment has been achieved even before reaching the maximum pressure stage, Perseus® A500 offers the possibility of

prematurely transferring to the decremental phase and to begin with gradual pressure decrease - all without having needed to exert the pre-set maximum pressure. During the decremental phase, compliance and tidal volume can be monitored during the pressure stages in order to determine patient-specific PEEP.

Monitoring success of recruitment manoeuvres.
The Perseus® A500 offers suitable ventilation monitoring for both recruitment procedures, where pressure level as well as compliance and tidal volume, respectively, are displayed. Comparison of lung mechanics before and after the manoeuvre, as well as during the current manoeuvre, facilitates the evaluation of the success of the recruitment. For multi-step manoeuvre, cursor functions allow for determining the optimal PEEP. Moreover, the Dräger Zeus® IE, Perseus® A500 anaesthesia workstations and the products of the Primus® family offer trend graphs for patient compliance, as well as pressure volume flow loops with the possibility of setting reference loops. These functions allow monitoring of the lung mechanics, particularly temporal changes, thus simplifying indication of a recruitment manoeuvre.

Dräger Infinity® Acute Care System (IACS) patient monitoring offers, in combination with Dräger anaesthesia devices, a dedicated analysis display that enables the monitoring, in parallel, of haemodynamic and ventilatory parameters. The combination of monitoring parameters can be configured freely, so that all values of clinical relevance are visible at a glance. Arrow indicators simplify assessment and a cursor function permits detailed analysis of the recruitment manoeuvre.

Dräger IACS patient monitoring – analysis view

CONCLUSION & OUTLOOK

Dräger is committed to support anaesthesiologists worldwide in their strive to protect their patients. We are aware of the need for systems and functionalities enabling anaesthesiologists to provide the best possible care in a complex and restrictive environment. To this day, Dräger offers a wide array of features helping to free up cognitive capacities and reduce the incidence of human error by displaying meaningful information and providing smart visualisations for a quick and profound clinical decision making.

1) Bohnet-Joschko S, Zippel C, Siebert H; Prevention of medical device-related adverse events in hospitals: Specifying the recommendations of the German Coalition for Patient Safety (APS) for users and operators of anaesthesia equipment; Evid Fortbild Qual Gesundhwes. 2015;109(9-10):725-35. doi: 10.1016/j.zefq.2015.06.001.

91 05 713 | 18.05-1 | BM | Subject to modifications | © 2018 Drägerwerk AG & Co. KGaA

CORPORATE HEADQUARTERS
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany

www.draeger.com

REGION DACH
Dräger Safety AG & Co. KGaA
Revalstraße 1
23560 Lübeck, Germany
Tel +49 451 882 0
Fax +49 451 882 2080
info@draeger.com

REGION EUROPE
Dräger Safety AG & Co. KGaA
Revalstraße 1
23560 Lübeck, Germany
Tel +49 451 882 0
Fax +49 451 882 2080
info@draeger.com

REGION MIDDLE EAST, AFRICA
Dräger Safety AG & Co. KGaA
Branch Office
P.O. Box 505108
Dubai, United Arab Emirates
Tel +971 4 4294 600
Fax +971 4 4294 699
contactuae@draeger.com

REGION ASIA PACIFIC
Draeger Singapore Pte. Ltd.
25 International Business Park
#04-20/21 German Centre
Singapore 609916
Tel +65 6308 9400
Fax +65 6308 9401
asia.pacific@draeger.com

REGION CENTRAL AND SOUTH AMERICA
Dräger Panama S. de R.L.
59 East Street, Nuevo Paitilla,
House 30, San Francisco Town
Panama City, Panama
Tel +507 377 9100
Fax +507 377 9130
servicioalcliente@draeger.com

Locate your Regional Sales Representative at:
www.draeger.com/contact