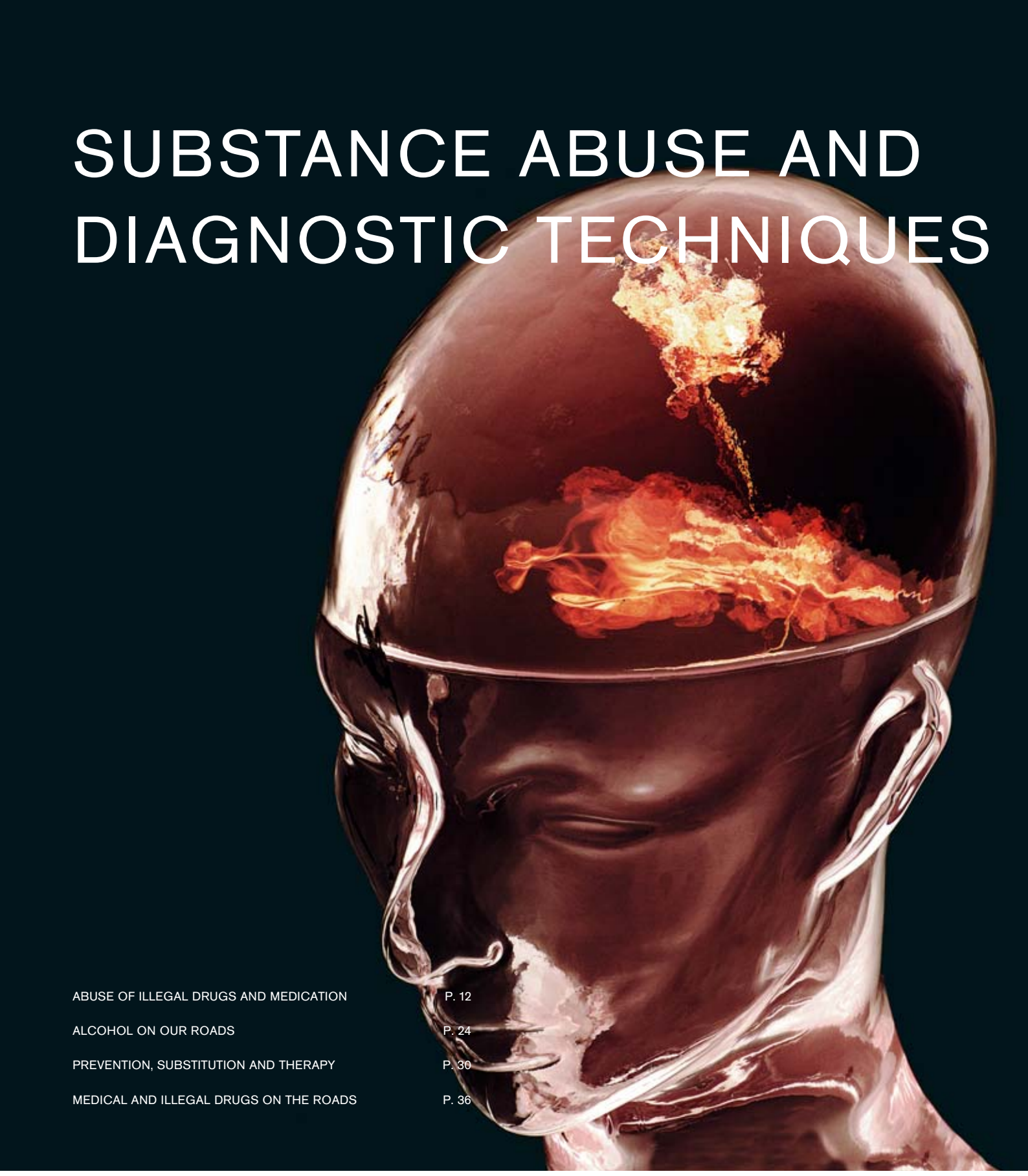
SUBSTANCE ABUSE AND DIAGNOSTIC TECHNIQUES



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Editorial

Drug abuse in the social context

When people talk about drugs, it always seems obvious what they mean. Often, however, it quickly becomes clear that the term can be used to refer to many different things. For instance, someone who enjoys a glass of wine or beer may well be unwilling to accept that their "tipple" is also classified as a drug, while tea and coffee drinkers will no doubt find it equally hard to understand that their "fix" counts as one of the common (legal) drugs.

In most societies, certain substances are tolerated as drugs, and intoxication and ecstasy are permitted within the framework of certain norms.

In distinguishing between hard and soft drugs, it is not only the drug's addictive potential that counts – the degree of psychotropic effect is also taken into consideration, as are health, political, cultural and economic aspects. Another classification which is just as common and just as problematic involves determining the legal status of drugs. Alcohol, for example, enjoys a high standing in some cultures (where an official reception without wine or champagne would be unthinkable), while in other regions it is strictly forbidden.

Dividing drugs up into natural and man-made substances is somewhat easier. Some parts of plants can be consumed as drugs without much in the way of processing, while others first need to be treated chemically before the desired narcotic effect is obtained.

If we look at how patterns of social consumption have evolved and at the prevalence of drugs such as alcohol, we can see that the popularity and consumption of these substances has been determined by social and economic circumstances. Archaeological research, for instance, tells us that people were brewing alcohol long before they started baking bread.

The history of drug development shows clearly that it was last century's technology drive and the huge increase in production that produced the phenomenon we see today, namely the socially and geographically widespread consumption of alcohol, tobacco and indeed illegal drugs. Tobacco and alcoholic drinks are now among the most readily available goods in many countries.

The consequences of "substance abuse", however, can be devastating not only for

the person concerned, but also for their families, friends and work colleagues, and indeed for the general public (e.g. on the roads).

Alcohol consumption – a mixed blessing

Alcohol in the form of fermented or distilled beverages is freely available (with few exceptions) as a legal substance, and drinking alcohol is deeply rooted in many different cultures. At the same time, alcohol is a cell toxin and a neurotoxin, and results in addiction. There are hardly any organs in the human body which are not damaged by excessive alcohol consumption.
Alcohol abuse became a social problem with the rise of the proletariat; at the beginning of the 20th century, public interest in alcohol-related problems waned as people were caught up in the world economic crisis and the First World War. In the second half of the 20th century the problem once again returned to the public eye as "alcoholism of the affluent classes". This dispensed with the stigma of it being an "evil vice" and made it, by definition, a pathological condition. Indeed, alcohol dependence is a serious illness from which it can take months to recover.
The mass consumption of alcohol and the problem of alcoholism, with its marked tendency to generate addiction, results in a much greater problem quantitatively speaking – in terms of the number of those affected and the associated health and social costs – than consumption of all other drugs combined!

Smoking: Russian roulette

Nowadays it is a well-known fact that smoking can cause illness and death, as well as accelerate many other diseases. In other words, many people, and especially the young, harm their health by smoking despite being aware of the risks. Tobacco consumption has now become the leading preventable cause of illness and death. As far as the frequency of consumption and the damage to health that it causes is concerned, tobacco is the number one drug.

Medicine: boon or bane?

Medicine not only cures illness, but is also a socially recognized and tolerated "drug". Prescription drug abuse is when medication is taken without medical grounds or in unnecessary quantities. In practice, such abuse usually involves psychoactive substances, especially barbiturates (sleeping pills), analgesics (painkillers), sedatives and stimulants. Substances containing benzodiazepines in particular, which can cause a low-dose dependence after just four weeks or so of regular consumption, are regularly taken over long periods of time.
Although prescription drug abuse is rampant in our society, it rarely receives much public attention. It is often very difficult to draw a clear line between normal (medically necessary) consumption and abuse. Six to eight percent of all prescribed drugs have some addictive potential.

Illegal drugs

Unlike with alcohol and tobacco, there is still some controversy as to whether "legal consumption" of cannabis products should in fact be possible, or whether such consumption should always be treated as substance abuse, though in the case of drugs with high addictive potential the concept of normal consumption is categorically ruled out. The fact that drugs such as cannabis and cocaine are illegal, for example, is the result of social appraisals of the use of these drugs in industrialized countries. Both cannabis and coca leaves have been known as remedies, cult and narcotic substances for thousands of years.

However, narcotic drugs also have a negative impact on the way an industrial society functions, and the consumption of illegal drugs is by no means a uniform phenomenon. Drug use can cover different substances which are consumed independently, in succession or in combination, and in varying quantities.

Monitoring abuse: testing and measuring

European countries generally base their drugs policy on the so-called "four-pillar model", i.e. repression, prevention, survival assistance and treatment. Today, Dräger Safety measurement technology is used in all four of these areas.

First and foremost, tests and measurements are performed to diagnose and detect substance abuse. Despite widespread preconceptions to the contrary, the majority of drug addicts do not live up to the classic image of a junkie or drunk. The number of unreported cases is extremely high (especially as regards alcohol and prescription drug dependence), and the addiction tends to go undetected for a long time. Those concerned appear to lead a well-ordered life, have a normal job and are often left alone with their problem.
In other words, diagnosing the problem of addiction or abuse is the first step towards helping the person concerned, e.g. by making treatment available. Both as regards diagnosis and further-reaching prevention, treatment and assistance measures, alcohol and drug tests constitute an indispensable measurement instrument for the attending doctor and in some cases even for the person concerned.
Monitoring activities (alcohol and/or drug tests) as part of various campaigns and programmes, e.g. traffic checks or medical examinations, can not only help detect substance abuse, but can also have a preventive – and in some cases even a teaching – effect. A person's inhibition threshold becomes greater the higher their risk of being discovered. Quick measurements which can be performed on site enable police to classify strange and dangerous behaviour exhibited by drivers and to judge the extent to which they can be made accountable for their actions. The situation is similar in a court of law where the accountability of offenders or the reliability of witness statements needs to be assessed. Drug monitoring programmes in prisons are used to detect any substance abuse by prisoners on temporary release, inmates and visitors.

What is more, alcohol and drug testing can help monitor a person's compliance with parole requirements or with the requirements necessary for them to re-obtain their driving licence. Drug testing also plays an important part in the investigations conducted by customs officials.

Monitoring of possible substance abuse is also extremely important in emergency medicine as it reveals whether particular conditions should be treated as the consequence of alcohol or drug abuse or whether they have other causes. In rehabilitation programmes, alcohol and drug tests can be used to check whether patients are "clean" and whether they are following their treatment plan. Testing and measurement systems for the detection of substance abuse in occupational medicine and at the workplace have gained an equally firm foothold.

At Dräger, we have devoted more than 50 years to the topic of breath alcohol measurement in all its technological diversity, in its various fields of application and with a wide variety of products. For over a decade, we have also been focusing on how to detect other drugs apart from alcohol, especially illegal drugs such as cannabinoids (marihuana, hashish), cocaine and its derivative, opiates and the designer drugs (speed, XTC, etc.) using saliva samples. In recent years, Dräger Safety has presented various new developments, products and services in this field. This special edition takes a closer look at the subject of drug testing and introduces the reader to monitoring systems and services which allow test subjects to undergo targeted, precise, hygienic and easy-to-use substance measurements.

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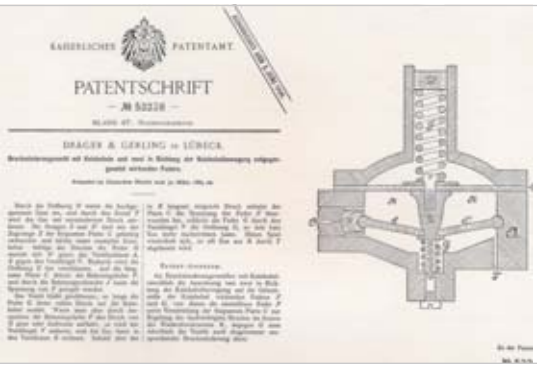
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Figure 1: Patent application for the “Lubeca” pressure reduction valve, dated 31 March 1889

From beer tap to breath alcohol measurement – over 110 years of Dräger and 50 years of Alcotest

How Dräger began

Even at the time of its establishment on 1 January 1889, the foundations for the Dräger company's success were already closely linked to the consumption of alcohol. Together with an associate, Heinrich Dräger founded a small shop-cum-workshop named "Dräger und Gerling“, which soon devoted its attention to carbonic acid pressure reduction valves for beer taps. Carbonic acid is used to expel the beer from the tap, and the valve was designed to bring the highly pressurized carbonic acid in a gas cylinder down to the pressure required in the beer barrel, allowing the beer to bubble gently out of the tap.

Local pub landlords frequently came to the workshop to complain about "faulty" pressure reduction valves, claiming that the flow of beer from the tap would regularly peter out. In the workshop, however, the valves were found to have nothing wrong with them. Closer inspection revealed that the inside of the valve was being cooled down by the expanding carbon dioxide to such an extent that the carbonic acid was freezing inside the valve, thus blocking it. Once the valve had been removed and warmed up, however, the beer was able to flow freely again and the valve was fully functional.

As a result of these findings, a reduction valve was designed in which sufficient warmth was supplied from the ambient air to the critical point, preventing the carbonic acid from freezing. The patented design of this invention, known as the "Lubeca valve“, soon proved to be superior to rival devices (Figure 1). For the first time, it was possible to tap the carbonic acid stored in compressed gas cylinders safely and without risk, on a continuous basis and at an even and controllable pressure, ensuring a constant supply of beer in pubs and restaurants. Soon after, in 1891, the company was therefore renamed "Lübecker Bierdruckapparate- und Armaturenfabrik Heinr. Dräger“ (Lübeck beer pressure apparatus and accessories factory Heinr. Dräger).

The early days of gas detection technology

Over the following years, the company, which in 1902 was renamed Drägerwerk, began to broaden its focus to include other applications for compressed gas technology. For instance, among other things respiratory protective devices with a supply of compressed air were manufactured, as were protective masks which were used, for example, by miners. In these masks, toxic carbon monoxide was removed by means of catalytic oxidation (combustion) of the carbon monoxide, turning it into perfectly safe carbon dioxide.

During development of filters, it was discovered that the oxidation of carbon monoxide generates considerable heat. This led to the idea that this heat could be measured as a way of determining the concentration of carbon monoxide [1]. By the end of the 1920s, this development resulted in the first Dräger carbon monoxide measuring instruments (Figure 2). The principle of measurement used in these instruments is still widely used today, for example to measure the concentration of combustible gases for explosion protection in many Dräger instruments.

Building on these early beginnings with the first instruments for the measurement of gas concentrations, Dräger has evolved to become one of the world's largest manufacturers of gas detection technology for professional applications, where concentra-

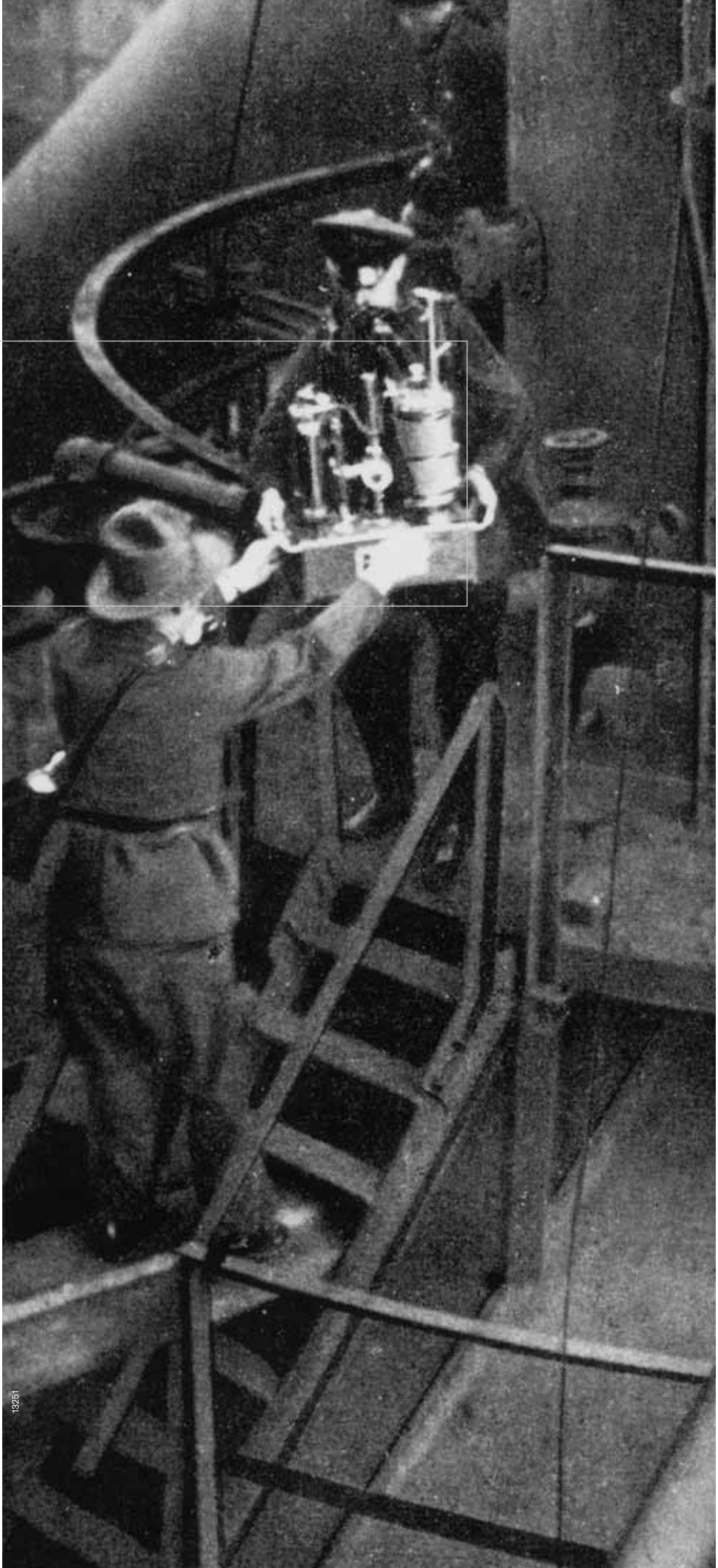

Figure 2: Dräger carbon monoxide measuring instrument in a smelting plant in the year 1929

tions of explosive and toxic gases, oxygen and indeed alcohol need to be measured.

Alcohol and road traffic

Even long before the invention of motorized vehicles, the effects of alcohol on people's perception and performance led to serious accidents. This resulted in 1872 in the issue of the British Licensing Act, which states that it is an “offence to be drunk while in charge on any highway or other public place of any carriage, horse, cattle, or steam engine” [2].
When motorization began, the number of road accidents involving drivers under the influence of alcohol rose. In a magazine published in 1904 [3], for example, 25 serious accidents involving automobiles are reported in which there were 23 fatalities and 14 serious casualties. 19 of the automobile drivers were under the influence of alcohol. As a result, the British Licensing Act extended its definition of an offence in 1925 to cover "any mechanically propelled vehicle“ [2].

Measuring breath alcohol concentration

Road traffic accidents caused by excessive alcohol consumption very soon showed

Figure 4: The first Alcotest tubes, developed in the year 1953, in use

that it was necessary to eliminate the risk situations resulting from alcohol-impaired driving. One of the most important and efficient methods of combating alcohol on the roads are frequent traffic checks. For this purpose, breath alcohol measurement is a much quicker and simpler method than blood sampling and analysis.

Initial fundamental research into the correlation between blood and breath alcohol concentrations was conducted as early as the end of the 1920s. In the work “Über die Ausscheidung des Alkohols mit der Expirationsluft” (On the expulsion of alcohol in exhaled air), Swedish scientists Liljestrand and Linde published the first simultaneously measured concentration curves for breath and blood alcohol in 1930 [4]. This paved the way for a quick and easy method of determining the extent to which a car driver was under the influence of alcohol by measuring the breath alcohol concentration.

Figure 3: Drunkometer by Hager from the year 1938 (photo: Honolulu Police Department, USA)

On the basis of this and other studies, the first breath alcohol measurement device, known as the "Drunkometer", was developed over the following years (Figure 3). This instrument used a wet chemical analysis procedure and was thus more reminiscent of a portable laboratory than an easy to use instrument.

The Alcotest tube

Although it was possible to determine a driver's breath alcohol concentration using the methods which had been developed, the procedures were not particularly practicable and, more importantly, were more or less impossible to use on site. Following World War II, there was a pressing need to carry out more frequent road traffic checks to combat the sharp rise in alcohol-related traffic accidents due to increasing volumes of traffic.

Consequently, when the "blow tube" developed by Dräger in 1953 was launched with its sampling bag to determine the breath alcohol concentration of road traffic users, the police immediately responded with great enthusiasm (Figure 4). This tube made it possible to conduct an objective on-site measurement which could be used to enforce further actions to secure evidence. The fact that the tubes were easy and safe to use made them well-known all over the world and popular among law enforcement officers and test subjects alike [5]. The "Alcotest®" brand name, which was coined at the time and protected for Dräger, has now become synonymous worldwide with breath alcohol measurement.

What prompted the development of this breath alcohol test is described in an

anecdote. One morning after a party in Dräger's test tube department, the chemists all accused each other of smelling most strongly of alcohol. To put an end to the debate, an objective and accurate method of measurement was needed – and this was how the Alcotest test tube came about, based on the many years of Dräger experience in the development of methods to measure gas concentrations.

The Breathalyzer

In the USA, Robert F. Borkenstein also presented his "Breathalyzer" in 1953: the first "easy to use" breath alcohol measurement instrument (Figure 5). This was a chemical laboratory instrument whose result was analysed electrically. The instrument was even recognized in the USA as a substitute for the blood sample, and continues to be used today – in somewhat modified form – in some states of the USA and Canada.
In the 1980s, Dräger took over production and sale of the Breathalyzer from the original manufacturer Smith & Wesson, and the instrument continued to be manufactured by Dräger until just a few years ago (Figure 6).

The handheld Alcotest 7310 instrument

Over the years, the requirements for accuracy, speed and test frequency, as well as effective and economical use, have increased considerably. Thanks to the huge advances in sensor technology, the chemical processes have been replaced by small, reliable sensors, making possible the development of reliable and easy to use breath alcohol measuring instruments .

The first outcome of these developments was the launch in 1980 of an electronic handheld instrument which used a so-called semiconductor sensor (based on tin dioxide) to determine the breath alcohol concentration [6]. The instrument, called the Alcotest 7310, was the first to display a measured value within several seconds to show the alcohol concentration. With its digital display of results, the instrument allowed easy, objective assessment, making it much easier to carry out – and boosting the acceptance of – alcohol checks.
Because of the semiconductor sensor used in the Alcotest 7310, with the limited long-term stability typical of such sensors, the instruments had to be calibrated within four weeks at the latest.

The handheld Alcotest 7410 instrument

In the area of sensor technologies, the development of electrochemical gas sensors in particular was dramatic in the 1980s, enabling a level of sensitivity, accuracy and, above all, long-term stability to be achieved which had previously been thought impossible. Within just a few years, electrochemical gas sensors completely replaced semiconductor gas sensors in most professional applications, for example the measurement of hazardous gases. This also resulted in a new generation of handheld detectors for breath alcohol instruments measurements.

The first member of the Alcotest 7410 family, one of the most successful handheld instruments in the world to date, was launched by Dräger in 1988 (Figure 7). It achieved its extraordinary measurement accuracy, reliability and its calibration interval of six months by using an electrochemical DrägerSensor [7]. In its different designs (Alcotest 7410 Plus, Alcotest 7410 Plus RS, Alcotest 7410 Plus com, Alcotest 7410 med), the Alcotest 7410 family is still the international standard for professional breath alcohol testing by the police and in industry and hospitals.

Figure 5: Robert F. Borkenstein with the Breathalyzer he developed in the year 1953 (Photo: Department of Criminal Justice, Indiana University, USA)

In 1996, the Alcotest 7410 Plus RS saw the dawn of the computer era in handheld instruments for breath alcohol measurement. Thanks to the RS-232 interface, the stored measurement results can be sent to a PC, where they can be analysed according to various criteria such as number of tests, measured concentrations or time of test.

In the year 2001 the family was enlarged to include the Alcotest 7410 Plus com, which set new standards in handheld instruments [8]. The instrument combines the sturdiness and measurement accuracy of all

Figure 6: Dräger Breathalyzer using wet chemical analysis procedure

Figure 7: Alcotest 7410 with an electrochemical sensor in the year 1988

Figure 9: The Alcytron prototype with an infrared optical sensor in the year 1978

Alcotest 7410 devices with complete text on a graphic display. Information for the user and tested person is no longer given in coded form but in plain text, greatly facilitating user-guidance and intuitive device use and making the instrument extremely convenient to use and operate. Texts can be viewed in a huge number of different languages and alphabets, including for example Vietnamese and Chinese (Figure 8).
Of course, development did not stop there. In 2003, for instance, an Alcotest measuring system has been presented which (the respective legal regulations permitting) will allow a handheld instrument to produce measurements which are admissible as evidence in courts.

Evidential breath alcohol measurement

As use of breath alcohol measurement became more widespread, many countries demanded improved measurement results to allow them to be used as evidence in courts and, as such, to be recognized as equivalent to a blood sample. This prompted the development of infrared optical DrägerSensors. The first trials with this technology were carried out back in 1978 with a prototype known as the Alcytron [9] (Figure 9). This led in 1982 to the stationary Alcotest 7010 breath alcohol measuring instrument (Figure 10). The infrared optical DrägerSensor located in the handset used a light wavelength in the range of 3.4 micrometres [10].
The disadvantages of the device, which was state-of-the-art at the time, were the size and weight of the handset containing the infrared optical sensor, the instrument's limited ability to distinguish alcohol from other substances possibly being exhaled by the tested person, and the high level of power consumption which meant that the instrument could only be used on a mains power supply.

Bild 8: Chinese display on Alcotest 7410 Plus com in the year 2002

The Alcotest 7110

In 1985, when the first generation of the Alcotest 7110 was introduced, the foundation stone was laid for a new family of stationary breath alcohol measuring instruments which were also suitable for mobile use. The integrated infrared optical DrägerSensor allowed residual alcohol in the mouth to be detected, and the light wavelength in the 9.5 micrometre range meant that highly selective determination of the breath alcohol concentration could be achieved. An integrated printer also allowed measurement results to be printed out immediately on site.
The further development of the Alcotest 7110 over the course of several generations, offering among other things much more powerful electronics and software, peaked in the Alcotest 7110 Evidential which since 1998 has marked a milestone in breath alcohol measurement (Figure 12). The instrument, which can be used in mobile and stationary applications, boasts a dual sensor system (infrared optical and electrochemical), breath temperature measurement, integrated printer, and pressure and volume sensors – its measurement results meet the strictest requirements worldwide and have set the standard in many countries [11]. In Germany, the Road Traffic Act and a judgement by the Federal Supreme Court have deemed the instrument's measurements equivalent in court to the results of a blood sample.

Interlock

Frequent police checks are an important and efficient method of reducing the number of road accidents caused by excessive alcohol consumption. A further step is only to allow a vehicle to be started once a breath sample has been submitted. This is

Bild 10: Alcotest 7010 with infrared optical sensor in the year 1982

Bild 11: Alcotest 7110 Evidential with infrared optical and electrochemical sensor in the year 1998

Bild 12: The Dräger Interlock, an alcohol ignition interlock device, in the year 1995

where alcohol ignition interlock devices, so-called alcohol interlocks, come in. Once installed in a vehicle, the engine can only be started if a breath sample containing no alcohol is given. Nowadays, such instruments are in widespread use, mainly in North America.
Dräger has applied its many years of experience in the development and production of breath alcohol measuring instruments to this area, too, resulting in 1995 in the launch of the first Dräger Interlock (Figure 11). This device is the successful outcome of Dräger's investment of its decades of experience in this new area of application for breath alcohol measurement [12].

50 years of Alcotest

In developing and launching Alcotest products, the Dräger company has returned to alcohol, to the beer tap, and therefore to the very roots of its more than 110-year history.

In 2003 Dräger was celebrating 50 years of Alcotest products. The company boasts a 50-year history in the development, production and sale of products for breath alcohol measurement. Today, Dräger Alcotest instruments are in use in every conceivable design worldwide. What started with the Alcotest tube has now evolved to include computer-controlled measuring instruments which prevent external influence and tampering during determination of the breath alcohol concentration [13].
As such, Dräger Alcotest instruments help improve safety on our roads. The technology has changed over the years, and the quality of the results and the ease of use have improved continuously – proud testimony to 50 years of the name Alcotest.

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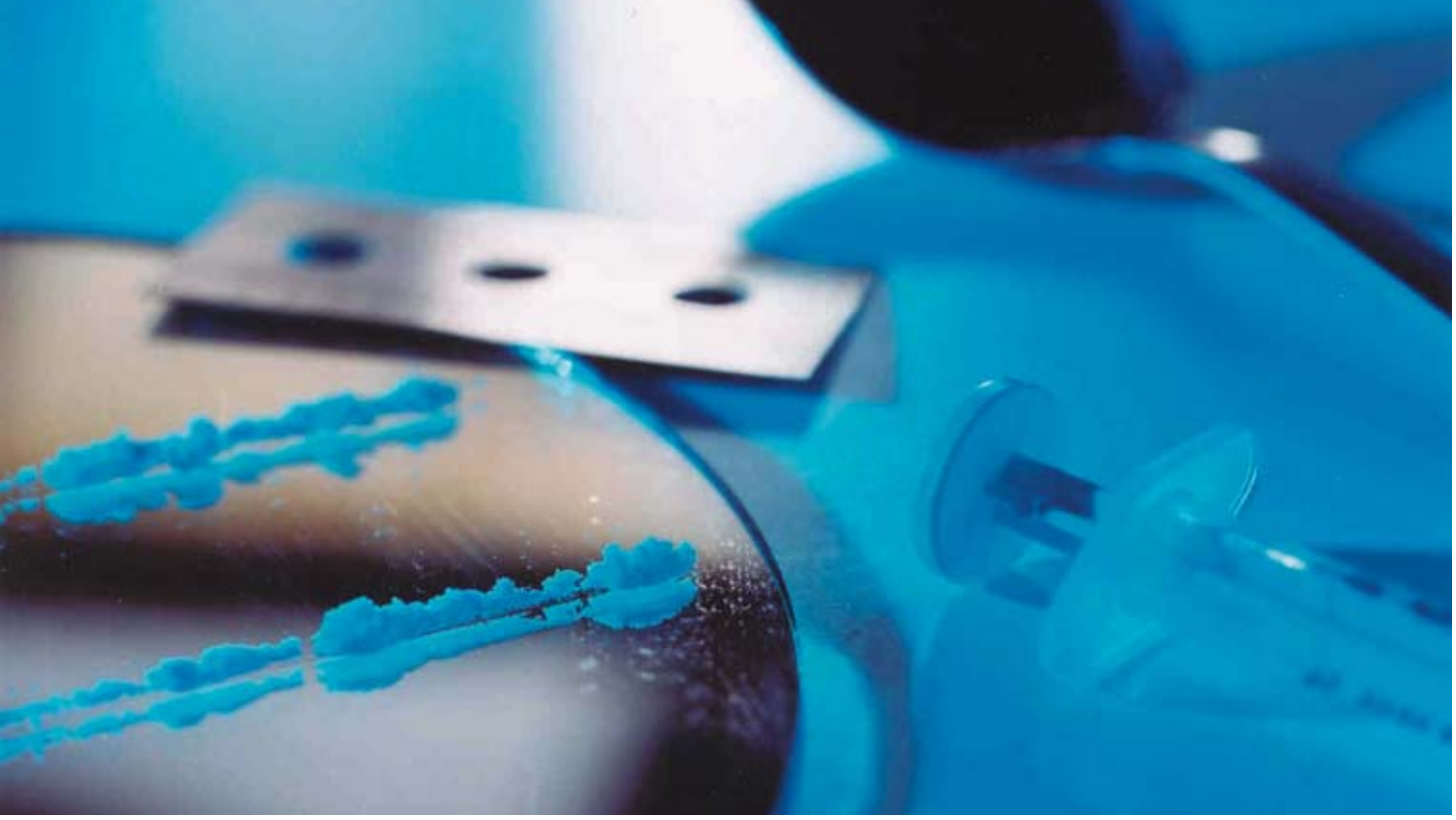
Indulgence, cure or abuse?

When people talk about drugs, they generally mean "natural, semi- or fully-synthetic substances which affect the central nervous system (CNS) and are taken with the purpose of bringing about a change in consciousness and/or experience". There are two essential factors operating in tandem when it comes to defining the word "drug" – a substance's pharmacological effect (as an objective property) and the way it is used or the reason for its use (as a subjective property). The psychoactive substances referred to in this article tend to have considerable addictive potential.

Alongside the most widespread of the legal stimulant drugs, namely alcohol and nicotine, the range of psychoactive substances which has been available since the 1960s in particular has widened considerably. Almost all of these substances, many of which were originally developed as pharmaceuticals, were classified as illegal by the western industrialized nations. At the present time, cannabis is the most commonly used illicit drug, with numbers of users increasing, especially among young people. In Germany, more than 10 tons of hashish and marijuana were seized in 2003. The consumption of party and fashion drugs like amphetamine ("speed"), MDMA ("ecstasy") and cocaine has also remained high. In 2003, more than a ton of cocaine was seized in Germany, and a total of nearly 500 kg of amphetamine and methamphetamine was confiscated in almost 4,000 separate incidents [1].

How illicit drugs affect people and the symptoms they cause vary greatly. Amphetamine ("speed") is similar in terms of its chemical structure to the human neurotransmitters adrenalin and dopamine. It is primarily taken in powder form and suppresses fatigue, reduces a person's need to sleep, curbs the appetite and lowers the aggression threshold. MDMA ("ecstasy") is usually taken in tablet form, causes changes in mood and also suppresses hunger, thirst and tiredness. Its widespread use in the rave scene is due in part to its ability to heighten the dance experience. The stimulating and de-inhibiting effect of cocaine induces people to continue using the drug until they are heavily psychologically dependent on it; typical of this drug is the need to increase the dosage. Cannabis products (hashish, marijuana) contain the active ingredient delta-9-Tetrahydrocannabinol, Δ9-THC, and bring

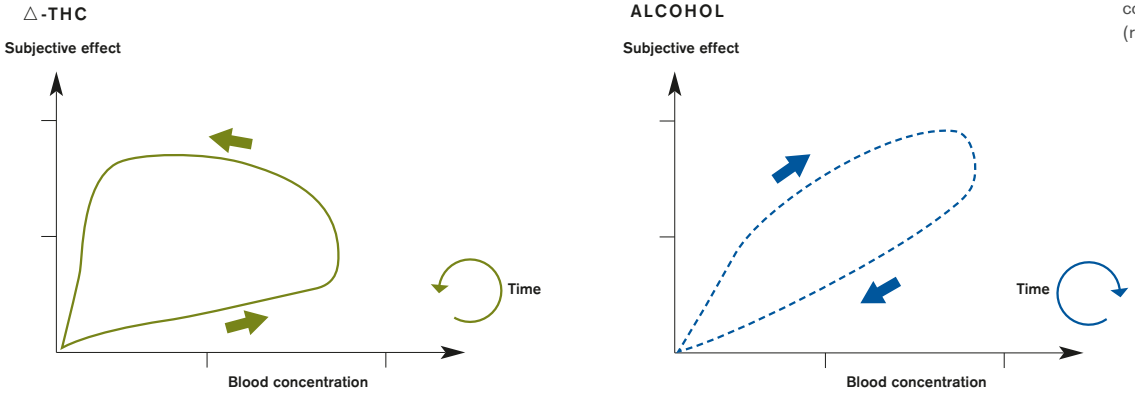


about acute changes in thinking and behaviour, though these can be perceived differently from person to person, and indeed each time the drug is consumed. Typically, the effects include slower movement and thought, reduced attentiveness, lessened grasp, euphoria, (unfounded) happiness, relaxedness, inertia, reduced drive, lack of drive or apathy, sleepiness, mood swings, dysphoria, irritability, and increased appetite. Especially if high doses of Δ9-THC are taken, hallucinations and visionary states can occur – these may manifest themselves in a distorted or lacking sense of time, space, person and situation. In addition, medical drugs such as painkillers, tranquilizers and sleeping pills are abused on a grand scale. Medical drugs are those pharmaceuticals which (in specific dosages) are used to cure, prevent or alleviate an illness. Since time immemorial, certain plants, plant extracts and animal substances have been used for these purposes, though in recent times mainly synthetic substances are used. A number of medical drugs – especially those which affect the CNS – can also be addictive. Benzodiazepines in particular, which are used as sleeping pills and tranquilizers to dispel fears and improve the mood, are often used for too long and in too high doses. It is presumed that most of the 1.4 million people in Germany who are addicted to medical drugs are dependent on benzodiazepines.

Pharmacological relations

Pharmacology, the branch of science which studies how chemical substances interact with biological systems, has a number of subdisciplines. Pharmacokinetics, for example, describes the changes in concentration of consumed substances and/or their metabolites in the organism over time. By observing pharmacokinetic processes such as the absorption, distribution and, finally, elimination of a biologically active substance, it is possible to determine how the organism reacts to the consumed substance.
Pharmacodynamics provides information about how a pharmacological effect is brought about after a biologically active substance has been consumed.
In order to be able to draw logical toxicological conclusions about the effects of a drug from the measured blood concentration, a parallel and, ideally, linear time progression of both curves (rise, maximum values, fall) would be useful. However, this type of relationship is generally not possible to determine for drugs and pharmaceuticals.
When a person smokes a joint, for example, the concentration of the active substance in the blood increases immediately, even though the effect is felt only very gradually. While the effect is still subjectively felt to be increasing, the blood concentration is already falling again. In other words, the effect lags somewhat behind the concentration progression of the active substance. It is only some time later that the relationship is reversed, with the effects decreasing faster than the active substance is eliminated from the blood. This relationship can be portrayed as an anticlockwise curve [2].

In the case of alcohol, the relationship between concentration and effect is exactly the opposite: in this case, the subjective effect at the beginning is felt to be greater than the concentration in the blood, while at the end the alcohol is broken down much more quickly than the time it takes for the effects to disappear. This time, the result is a clockwise curve [3].
The different progressions of effect and concentration are attributable not only to



Concentration plotted against effect following smoking of a cannabis cigarette (left) and after consumption of alcohol (right).

the chemical properties of the consumed substances, but also to the way they are consumed. The effects of smoking cannabis, for instance, are felt within minutes, peak within 15 minutes, and start to fade around 30 minutes after smoking. On average, the intoxicating effects are over after two to three hours. If cannabis cakes ("space cakes") are eaten, the effect is felt with some delay, some half an hour to two hours after consumption – making it much more difficult to control the intoxicating effect.
If several different substances are in the body at the same time (alcohol and drugs, alcohol and medication, different types of medication), the substances can interact to add together or even multiply the different individual effects, though in some cases they can weaken or even (temporarily) cancel each other out. This means, however, that it is virtually impossible for a person to subjectively "plan" their degree of intoxication or for somebody to assess the behaviour of the intoxicated person.

Analytical methods

Which analytical methods to use is dictated first and foremost by the application. The following factors need to be taken into account [4]:

- Which substance or metabolite profile is likely to be found in the material to be analysed?
- Which analytes need to be determined to draw which conclusions?
- Which analytical requirements does the intended method meet?
- To what extent can the intended method be routinely used?

Immunological screening tests

To reduce the number of analyses that need to be carried out, the samples can be subjected to an immunochemical screening test. This allows samples to be preselected quickly on the basis of the presence of specific substances or substance classes, with a high level of sensitivity, and without significant preparation.
Immunological testing has its origins in the USA, where immunoassays have been widely used for drug detection purposes – as well as in toxicology – since the end of the 1980s within the framework of pre-employment and workplace testing for drug use. Accordingly, manufacturers of immunoassays base their "positive" and "negative" cut-off values on American decision-making criteria, i.e. the guidelines of the NIDA [5].
All assays take advantage of the antigen-antibody reaction principle, according to which the analytes compete with antigens to bind to specific antibodies. The number of immune complexes formed by the antibodies and analytes is an indication of the analyte concentration in the sample. The antibody-antigen bond, however, is not directly accessible for analysis in most immunoassays. This problem is solved by coupling one of the two components, either the antigen or the antibody, to an easily detectable "label". Enzymes (biocatalysts), dyes, fluorophors and, though less and less often, radioactive components are examples of possible labels [6].

Besides being used in urine analysis, immunoassays can also be used to detect drugs in other bodily materials. For example, microtiter plate tests have been on the market for a few years which allow direct and highly sensitive enzyme-immunochemical detection of drugs and metabolites in untreated whole blood or serum. No recommended cut-off values are (as yet) available. Immunoassays are a useful way of determining whether samples contain drugs, but their results must be confirmed by other reliable methods offering a higher degree of specificity, as this is the only way to ensure reliable identification and precise quantification.

Confirmatory analysis

Reliable quantitative determination of different drugs in a complex matrix such as serum demands the use of a selective method. Because of the low concentrations (in the nanogram range) of drugs in the blood, and indeed in oral fluid, complex analytical

methods have to be employed which allow measurements to be performed close to the detection limit.
The relevant literature describes numerous methods of identifying and quantifying analytes in physiological samples, though preference tends to be given to a combination of gas chromatography and mass spectrometry with stable isotopes as internal standards. Gas chromatography mass spectrometry (GC-MS) has long been known as a "definitive method" which is "correct" and specific; i.e. it delivers a definitive (correct) value as the best approximation to the "true value" [7]. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in the USA also list GC-MS as a "confirmatory drug test" [5]. Another definitive method which is used is liquid chromatography (LC), likewise in conjunction with a mass spectrometric detector.

Sample material

To determine whether pharmaceutical or narcotic substances are present in the body, toxicological analyses can be performed using different bodily materials. The materials should be chosen to match the requirements of the particular application; oral fluid and blood, for instance, can be used to detect recent consumption, while hair gives a clearer picture of consumption longer ago.

Blood

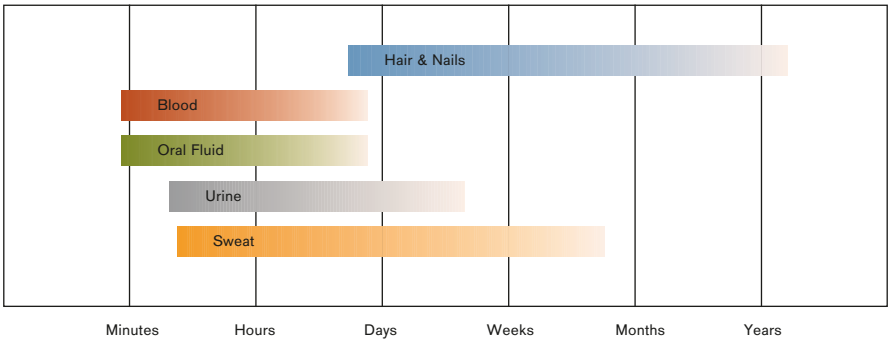
Blood is very well suited to testing for drugs and medication because, right from the outset, it contains the pharmaceutical or narcotic substance at the point the substance is introduced into the body and then transports it to all tissues, including the places where the substance takes effect and the organs which expel it once again from the body. Blood cannot be tampered with, has a fairly homogeneous composition, and the concentration of the substance is in a state of dynamic equilibrium with the concentration of substances absorbed into the central nervous system and, therefore, regarding any effect – at least to a limited extent. For all these reasons, blood is the only sample material which fulfils the German legal requirements of § 24a Subsection 2 of the Road Traffic Code. Since Germany operates a policy of "obligatory tolerance", a blood sample can be ordered by police officers if a traffic offence is committed. Taking of a blood sample, however, is a highly invasive process and therefore not suitable for conducting at the roadside.

Urine

Testing a urine sample can serve as a complement to a blood analysis. Urine's advantage as a sample material is that it can generally be provided by test subjects in larger quantities without the need for invasive techniques. As a rule, any foreign substances and their metabolites can be found in a higher concentration than is the case in blood, and can be detected for longer.
The broader metabolite profile can also provide additional information. One disadvantage, however, is the fact that the results of urine testing are only comparable to blood test results to a limited extent.
For example, measurable concentrations can usually be found in the blood immediately after consumption, yet the processes by which the drugs are broken down in the body mean that they cannot yet or can hardly be detected in the urine. On the other hand, a positive urine result does not necessarily point to very recent consumption; in the case of cannabis consumption in particular, THC carboxylic acid, which is the main metabolite used for detection, can be found in the urine even after several weeks.
The fact that urine testing requires suitable facilities in which the test subject can provide a sample often entails a great deal of time and personnel. It is impossible not to intrude upon a person's privacy if supervised sampling is required. It is also possible for the test subject's urine sample to be tampered with in many different ways, and indeed a sample is not always possible for various reasons. In other words, although urine is in principle a suitable test medium for detecting drug consumption, it is not practicable, and is not permitted by law in many countries.

Saliva / Oral fluid

(Physiological) saliva is colourless and transparent, low in viscosity and produced by the salivary glands situated in and near the oral cavity. Every day, these glands produce around 1 to 1.5 litres of saliva.
Samples of oral fluid (which is slightly different from saliva) provide detailed information



Analytical detection window for different sample materials [8].

about a person's current state of drug influence because, like blood samples, they correlate more accurately with the time of drug consumption and the extent of the effect than urine samples. It is also easier to obtain an oral fluid sample from a person than a urine sample, as there is no serious invasion of their privacy and the sample can therefore be obtained directly at the test site under constant supervision, without the need for any special facilities. As a result, far less time and far fewer personnel are involved in performing the test than is the case with urine testing. What is more, tampering on the part of the test subject is virtually impossible. Experience has shown that those tested, especially people suspected of driving under the influence of drugs, are generally much more willing to undergo an oral fluid screening test than a urine screening test.

Hair, fingernails and toenails

Material containing keratin such as hair and nails can also be used for the purposes of analysis. Because drugs are incorporated into the keratin structure, information about the "drug history" of the person under investigation and, to some extent, about their consumption can be obtained, taking the average rate of hair growth into account (approx. 1 cm per month). This does not provide any details of recent drug consumption, however, so no conclusions can be drawn as to whether a person is actually under the influence of drugs. Hair and nails do not represent suitable sample material for screening tests.

Discussion

In today's society, drug and medication abuse is being taken increasingly seriously. Analytical proof is thus also becoming increasingly important to allow preventive action to be taken, and to make boundaries clear to drug abusers through the use of sanctions.

Alongside laboratory-based analytical methods, it is those analytical techniques which are easy to use and can quickly produce a result which are particularly useful for on-site use. Drug screening tests in particular can be crucial in providing a quick and reliable qualitative indication of drug consumption. The requirements which such tests need to meet are quite different to those placed on instruments used in a laboratory. The test conditions in a chemical or medical laboratory are completely different to those, for example, during a "roadside traffic control". Testing at night, in bad weather, in chaotic situations etc. has a huge influence on the way a test is performed and does not reflect a test system's usability and reliability under ideal, reproducible lab-

Comparison of oral fluid testing with blood and urine testing for drugs of abuse [9].

		Oral fluid	Blood	Urine
Sample collection		Non-invasive	Highly invasive	Intrusion of privacy
Principle analyte		Parent drug and/or metabolites	Parent drug and/or metabolites	Metabolites
Analyte concentration		Low	Low to moderate	Moderate to high
Interpretation	1	Can be used to determine pharmacokinetic parameters	Can be used to determine pharmacokinetic parameters	Limited use in pharmacokinetics
	2	Potential correlation with impairment	Potential correlation with impairment	No correlation with impairment
	3	Used to estimate blood levels and free drug fraction		Cannot be used to estimate blood levels
Potential problems	1	Contamination from smoke, intranasal and oral administration	Limited sample availability	Possibility of adulteration
	2	Changes in pH during collection may change saliva to plasma concentration ratio (S/P ratio)		Changes in pH of urine during storage
	3			Drug excretion influenced by pH

oratory conditions (good lighting, room temperature, trained laboratory personnel etc.). This also affects the sample material; while the samples are treated in the laboratory (freezing, centrifugation etc.) for ease of analysis and can thus be standardized to a certain extent, such methods are generally not available on site, and this needs to have been taken into account as far as possible during development of the test system. A drug screening test system must be based on a principle which reflects the problem situation and, despite the potential difficulties which can occur during a road traffic control, for example, need to function precisely within clearly defined error limits.

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How to determine the alcohol concentration?

Alcohol and society

Alcohol, loved by some and cursed by others, is appreciated by most people as a means of stimulation and relaxation. We all know that consumption of alcohol has a negative impact on our perception and impairs our performance.

However, this change in state does not necessarily need to be unpleasant, and it is not without reason that alcohol plays an important "supporting role" in our social life. Alcohol stimulates, inspires, liberates and exhilarates. It removes inhibitions and makes establishing contact easier. Alcohol is missing at no celebration, at no reception, at no banquet. Alcohol is a firm fixture of our everyday life, and has been for many centuries.

Over the centuries, however, the requirements placed upon us in our social lives have changed considerably. Today we live in a modern world in which speed and technology define our daily life. Alcohol can be pleasant and fun, but the consumption of alcohol also holds many dangers.

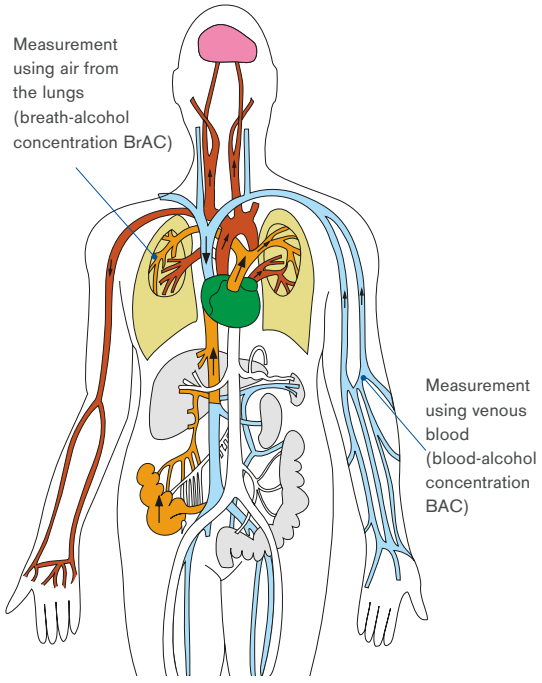
Road users under the influence of alcohol

When a person's consciousness is clouded by alcohol, this exposes us to many risks. Nowadays, we often encounter situations which demand our concentration and swift reactions. Who can tell how much alcohol is in his or her blood after two glasses of wine?

Only our conscience can help us decide how much "too much" is, yet it is precisely our conscience which becomes increasingly unable to function with each sip of alcohol. In Germany, for example, 70,000 road accidents involving people under the influence of alcohol are recorded each year. The proportion of people killed and seriously injured in these accidents is particularly high, and for more than 10,000 people in the European Union, and more than 15,000 people in the USA, the accident proves fatal. Every single accident which occurs due to excessive consumption of alcohol is one accident too many!

Such accidents show us where the limits are, making it clear what the difference between moderate and excessive can mean. Our sense of responsibility towards ourselves and others decides how we answer the question "alcohol, yes or no?".

Figure 1: Diagram of alcohol distribution in the body



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We all have a duty to accept this responsibility to prevent risk situations and dangers from occurring in the first place. However, only accurate, unmistakable proof of alcohol can show where the limits are, and this accurate proof can be obtained only by means of technical apparatus.

The physiology of alcohol

After drinking, the alcohol, or to give it its more accurate chemical name, ethyl alcohol or ethanol, is taken up by the blood in the gastro-intestinal tract and transported, via the heart and the lung, to the arteries of the brain. From the heart the blood is circulated around the rest of the body, into the arteries of the arms for example. From there it is distributed throughout the tissue and, finally, flows back through the veins.

Effects on reaction speed

Once alcohol reaches the arteries of the brain, it affects our speed of reaction and, in sufficient quantities, instantly provokes unusual, alcohol-related (driving) behaviour. The extent to which the speed of reaction is affected determines whether a person can still safely drive a car or whether there is an increased risk of accident.

To judge whether or not a person is fit to drive would require a method of directly measuring this reduction in reaction speed at the roadside, but this is too expensive to be a viable option.
To obtain nevertheless a useable procedure, "auxiliary variables" are used which permit an indirect conclusion to be drawn about a person's speed of reaction: a sample of air from the lungs or a sample of venous blood from the inside of the elbow is taken and its alcohol concentration determined.

Henry's law

The alcohol concentration is measured using air from the lungs or venous blood (Figure 1).
In accordance with Henry's law, diffusion processes, which are also what causes oxygen to be taken up in the lungs, achieve a balance between the alcohol concentration in the blood in the lungs and the alcohol concentration in the air in the lungs. The breath-alcohol measurement involves directly determining this concentration.

From the heart, the blood is circulated around the rest of the body, into the arteries of the arms for example.

From there the blood is distributed throughout the tissue and, finally, flows back through the veins. A sample of this venous blood is taken from the inside of the elbow and used to determine the blood alcohol concentration indirectly by means of a further multistage procedure (Figure 2).

Alcohol screening test

When determining a person's breath-alcohol concentration, a distinction is made between a preliminary screening test and an evidential analysis. A screening test is used by the police officer at the roadside to help decide objectively whether, if a particular limit is exceeded, an evidential breath-alcohol analysis needs to be carried out afterwards or whether a blood sample will be taken.
Alcohol screening tests are performed using Alcotest tubes, in which chemicals are discoloured by the alcohol in the breath (Figure 3), or using electronic hand-held instruments (Figure 4).

The familiar Alcotest tube with the sample bag is probably the oldest method of obtaining proof of alcohol in a screening test. However, requirements with regard to accuracy, speed, test frequency and effec-

tive and economic use rose considerably over the years. A screening test must be able to be performed swiftly and supply accurate results, and today mainly electronic devices are used.

Evidential measurement

After a positive screening test an evidential alcohol analysis must be performed. Lawmakers in different countries have set appropriate limit values for the two procedures, i.e. breath and blood alcohol analysis. The breath-alcohol concentration (BrAC), a gas concentration, is expressed for example in milligrams of ethanol per litre exhaled air (mg/l). The blood alcohol concentration (BAC), a liquid concentration, is expressed in per mille (‰) and refers to the amount of ethanol in grams in each litre of blood.

In many countries the lowest limit value which constitutes an offence is a blood alcohol concentration of 0.5 per mille (‰), the corresponding limit for breath-alcohol concentration being 0.25 milligrams per litre (mg/l) of exhaled air.

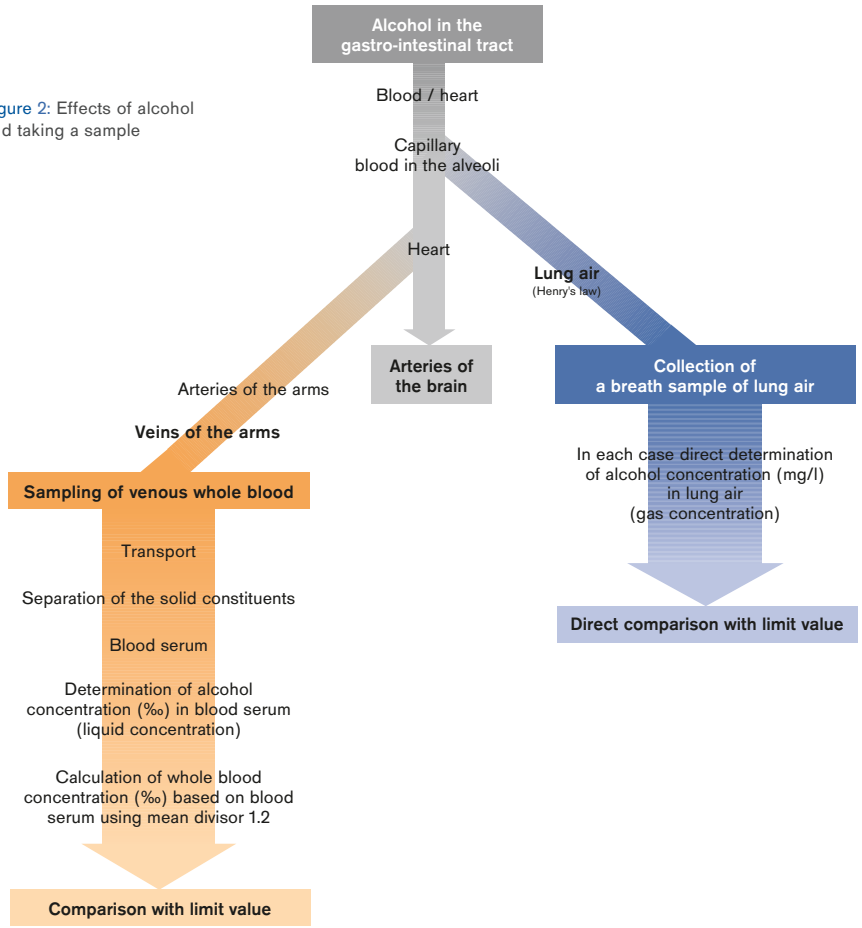


Figure 2: Effects of alcohol and taking a sample

Breath-alcohol concentration – a more accurate measure

Even though the limit values for both procedures may be equivalent from a legal viewpoint, the breath-alcohol concentration nevertheless offers a more direct measure of actual impairment of driving ability.

This is because of the path that alcohol takes through the body. From the place where the breath sample is taken from the lung, the blood transports the alcohol via the heart directly to the arteries of the brain, where the rapid increase in alcohol concentration impairs speed of reaction. Before the blood sample can be collected from the venous blood inside the elbow, however, the blood containing the alcohol is first distributed in tissue throughout the body.

A further advantage of the breath-alcohol analysis is that the alcohol content can be determined directly and documented immediately, even on site, for instance at the roadside.

Measuring the breath-alcohol concentration

Modern breath-alcoholmeasuring instruments usually determine the breath-alcohol concentration using two different measuring systems: an infrared sensor or an electro-

Figure 4: Alcotest 6510 in use

chemical sensor. Screening devices like the Dräger Alcotest 6510 use the electrochemical system of measurement.
In evidential analysers like the Dräger Alcotest 7110, both systems are used at the same time. By using two measuring systems with different analytical specificity, the device is able to reliably detect any interfering substances which may be present in the exhaled air and which might influence the result in any way, such as petrol, paint or solvent vapours.

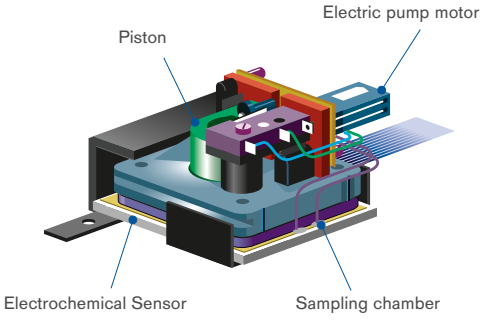


Figure 5: Electrochemical measuring system

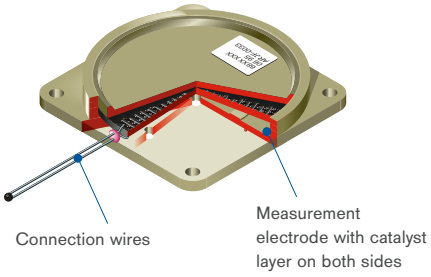


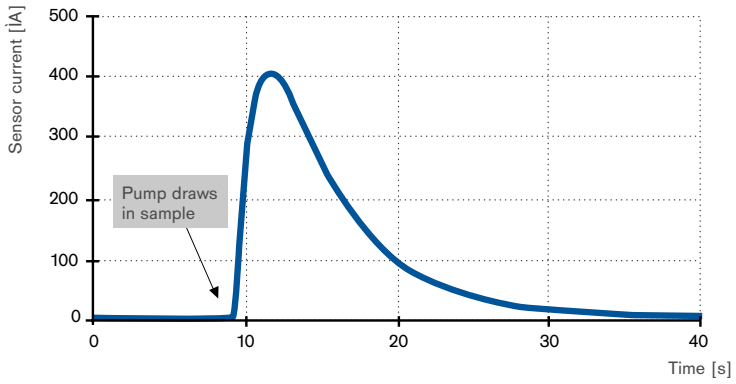
Figure 6: Cross-sectional view of an electrochemical sensor

Figure 3: Test tubes

The electrochemical measuring system

The sampling system in an electrochemical measuring system (Figure 5) conveys a sample of air with an exact volume to the electrochemical sensor (Figure 6). The sensor selectively and highly accurately analyses the breath sample for the presence of ethanol.
The sensor contains a membrane which is soaked in electrolyte and carries the measurement electrode and the counter-electrode. The electrolyte and the electrode material are chosen such that the alcohol to be analysed will be electrochemically oxidized on the catalyst layer of the measurement electrode. The electrons released by the reaction at the electrode cause a current to pass through the connection wires to the device's electronics (Figure 7). When the sensor current is analysed, the entire electrical charge released by the electrochemical reaction is determined, as this depends on the alcohol content in the sample chamber. This coulometric measurement method gives the sensor its particular long-term stability.
The electrochemical sensor only reacts with this high level of specificity to alcohol. This means that acetone, for instance, which is sometimes to be found in the air exhaled by diabetics or persons on a starvation diet, cannot distort the measurement result, as ketones do not react at the electrodes. This prevents any false-positive measurement results.

Figure 7: Sensor current of the electrochemical sensor during analysis of a breath sample containing approx. 0.5 mg/l of ethanol



The infrared measuring system

In an infrared optical sensor (Figure 8), a light source emits light at different wavelengths (colours) in the infrared range of the spectrum (i.e. not visible to the human eye). In the schematic diagram (Figure 9), the colours of visible light are used rather than the invisible infrared spectrum. The light passes through two windows and an interference filter which only allows penetration of certain wavelengths (the green light in the diagram). A detector measures the intensity of the incoming light and transmits a corresponding signal to the device's electronics system. If a gas (ethanol, for example) which absorbs part of the light at a particular wavelength (the green light in the diagram) is present between the two windows, the light intensity measured by the detector will drop, as will its electrical output signal. The higher the alcohol concentration, the more the signal will be reduced, which is thus a measure for the alcohol concentration.

Breath temperature

The alcohol concentration in the exhaled air (BrAC) increases as the body temperature and exhalation air temperature rise, due to the fact that an increased body temperature causes more alcohol in the lungs to evaporate out of the arterial blood in the lungs into the lung air. This takes place in accordance with a fixed physical principle known as Henry's law. Furthermore, as the body temperature rises, the exhalation air in the upper airways loses less of its alcohol concentration.

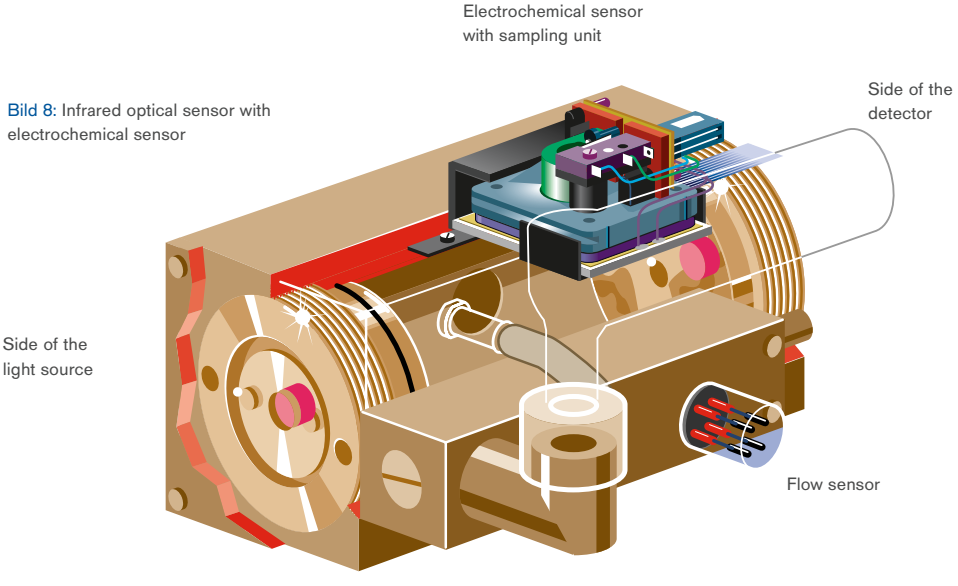
For this reason, some countries (Germany, for example) require measurement of the breath temperature when a sample of breath is given for evidential measurements.

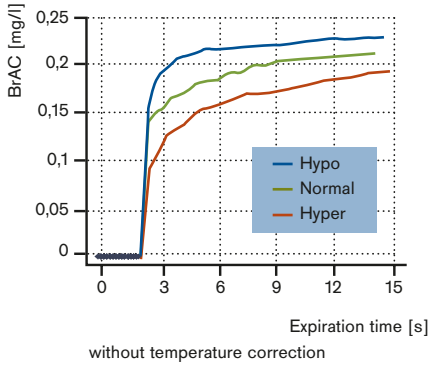
When calculating the measurement result, breath temperature sensors are used to always relate the breath-alcohol concentration to a fixed exhalation temperature of 34 °C, ensuring that persons with for example a higher than normal body temperature are not disadvantaged by a higher measurement result.

Ways to breathe, hyperventilation and hypoventilation

How the test subject breathes directly before giving the breath sample, and the ambient temperature, also have an influence on the measurement of the breath-alcohol concentration at the end of the exhalation. For instance, if the test subject hyperventilates (breathes excessively) or if ambient temperatures are low, the area of the mouth and throat and the windpipe are cooled to below normal levels. This causes the temperature of the exhaled air to fall and, consequently, the uncorrected breath-alcohol concentration is lower.

Bild 8: Infrared optical sensor with electrochemical sensor





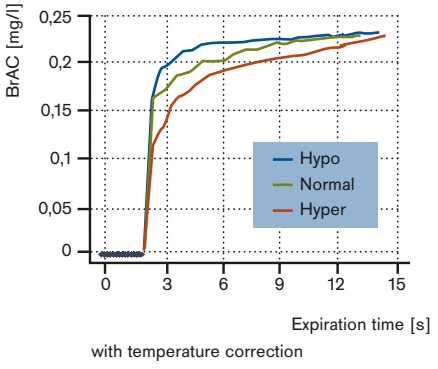


Figure 10: How different ways of breathing affect the breath- alcohol concentration (BrAC) (Source of diagrams: Prof. Slemeyer, Giessen-Friedberg University of Applied Sciences, Germany)

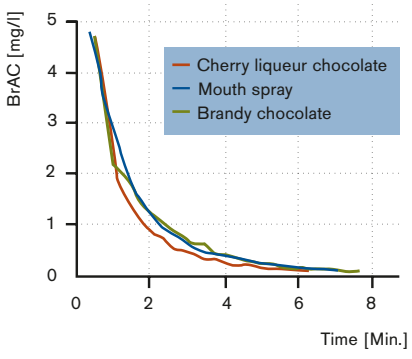
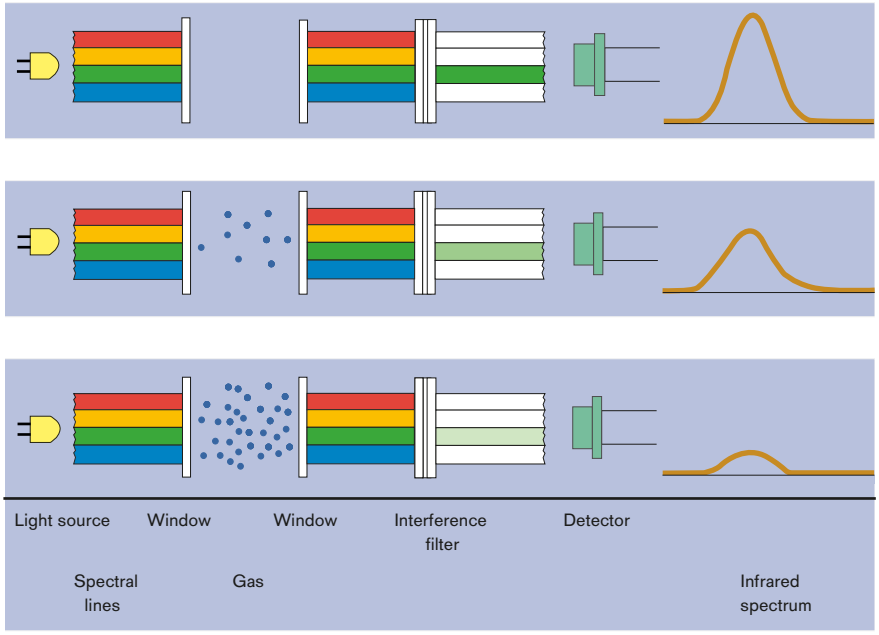


Figure 11: Decrease in breath-alcohol concentration over time following consumption of alcoholic substances (Source of the diagram: Prof. Slemeyer, Giessen-Friedberg University of Applied Sciences, Germany)

Figure 9: Schematic principle of measurement of the infrared optical sensor



Likewise, hypoventilation (shallow breathing) or high ambient temperatures can increase the temperature of the breath and thus result in a higher uncorrected breath-alcohol concentration. If on the other hand the actual measured breath temperature is used to correct the final result and relate it to an exhalation temperature of 34°C, the way the test subject breathes and the ambient temperature will not affect the result of the measurement (Figure 10).

Mouth alcohol

If shortly before the breath-alcohol concentration is measured the test subject consumes a substance containing alcohol (liqueur-filled chocolates, for example, or a breath freshener containing alcohol), the exhaled air absorbs alcohol not only from the lungs, but also from these substances in the upper part of the mouth and throat. As a result, the alcohol concentration detected in the exhaled air will be higher than the concentration in the lung air. However, within a few minutes this effect is completely cancelled out as the remaining alcohol in the mouth is taken up by the saliva or absorbed into the body (Figure 11). Waiting for at least 10 minutes before the measurement is performed and, possibly, comparing the results of the two individual measurements at intervals of two to five minutes can exclude the possibility of residual alcohol in the mouth influencing the final result.

Reliability of the measurement results

The various measuring systems now available to determine the breath-alcohol concentration have reached a very high level of technological advancement, guaranteeing reliability even under difficult conditions. Precision instruments allow the exact and unmistakable detection of alcohol, neutralizing risk situations and preventing danger.

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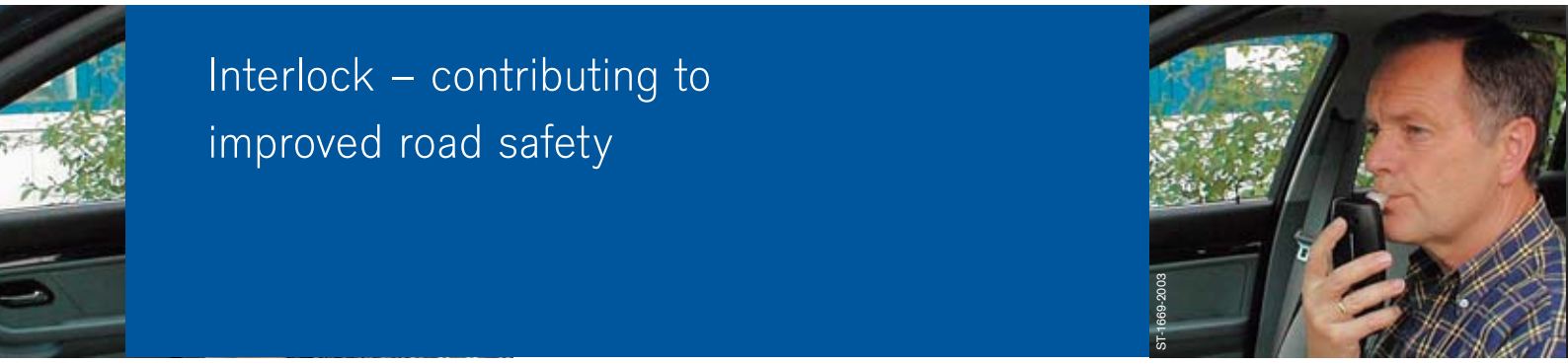
Figure 2: Submitting a breath sample to an interlock



Interlock – contributing to improved road safety

Every year, more than a million people worldwide lose their driving licence as a result of driving under the influence of alcohol. In Germany, for example, there are 70,000 road accidents a year involving people who are alcohol-impaired. For more than 10,000 people in the European Union and more than 15,000 people in the USA, these alcohol-related accidents prove fatal.
In view of the statistics regarding road traffic accidents and fatalities attributable to alcohol consumption, which remain worryingly high worldwide, attempts have been made in recent years to find ways to reduce the figures. In North America, for instance, large numbers of so-called alcohol interlocks (breath alcohol ignition interlock devices, BAIID) are used to prevent alcohol-impaired drivers from starting and driving their vehicles.
In most US states, interlocks have been a legal requirement for offenders who have been prosecuted for driving under the influence of alcohol, and today some 70,000 interlocks from different manufacturers are in use. Some Canadian provinces have also chosen to use interlocks in drink-driving offender programmes, while Australia and a number of European countries – Sweden and Finland, for example – have already introduced such programmes or have plans to do so.
The European Commission and the Council of the European Union are also looking into the question of how to raise safety standards on Europe's roads and, in particular, how to reduce the number of accidents caused by alcohol. The Council of the European Union, for instance, has decided to investigate the "scope for using devices which prevent the engine from starting if the maximum blood-alcohol level authorised at national level has been exceeded“ [1].
The worldwide experience of interlocks to date and recommendations for countries looking at introducing this system are described in considerable detail in a position paper published by the International Council on Alcohol, Drugs and Traffic Safety (ICADTS) [2]. Furthermore, the European Commission has ordered a feasibility study to be carried out to investigate the introduction of alcohol interlocks [3].

What is an interlock?

An interlock is a breath alcohol measuring instrument with vehicle immobilizer (Figure 1) which can be easily installed in a motor vehicle. Before the vehicle can be started, a

Figure 3: Interlock installed in a vehicle

Figure 1: Dräger Interlock XT

breath sample has to be given. Once the breath alcohol measurement has been performed (Figure 2), the interlock prevents alcohol impaired drivers from starting the engine.
An interlock comprises two main components: the breath alcohol measuring instrument with the measuring system and with the display, which is situated inside the vehicle (Figure 3), and the central unit which is generally installed under the dashboard and allows or prevents current being supplied to the vehicle's starter system. When the ignition is switched on, the interlock requests a breath sample from the driver (Figure 4). The result of the breath alcohol concentration measurement determines whether the vehicle's starter is released and the engine can be started.

Dräger Interlock

The Dräger Interlock XT was developed on the basis of Dräger's 50 years of experience in the area of breath alcohol concentration measurement. The device meets all worldwide interlock requirements, offers the greatest possible convenience for the user and is even tamper-proof – thus setting new standards for alcohol interlocks.

Measuring the alcohol concentration

A reliable interlock these days uses an electrochemical sensor to determine the breath alcohol concentration. The sampling system conveys a breath sample of a precisely defined volume to the electrochemical sensor similar to the one used in the screening devices [4,5] and evidential instruments [6] of the Alcotest family. The sensor determines the ethanol content of the breath sample selectively and with a high degree of accuracy.

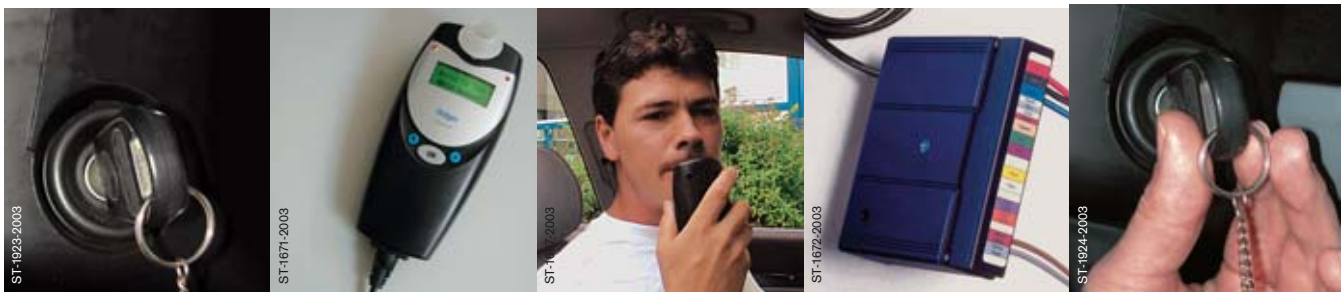
The sensor contains an electrolyte-soaked membrane which carries the measurement electrode and the counter-electrode. The electrolyte and the electrode material are chosen such that the alcohol to be analysed is oxidized electrochemically on the catalyst layer of the measurement electrode. The electrons released from the reaction at the electrode dissipate as current through the connecting wires to the instrument's electronics. When the sensor current is analysed the entire electric charge generated during the electrochemical reaction is determined. This coulometric measurement method gives the sensor its particular long-term stability.

The electrochemical sensor only reacts with high specificity to alcohol. As a result, acetone, for example, which can be found in the breath of diabetics and those on starvation diets, cannot distort the measurement result because the ketone group does not react at the electrodes. This prevents any false-positive measurement results.
During development of an interlock, particular attention must be paid to ensuring that the instrument will be ready for use quickly, as car drivers find long waits after switching on the ignition particularly annoying. At normal or high ambient temperatures, the Dräger Interlock XT is ready for use within just 10 seconds. To allow a quick and reliable measurement at low temperatures too, the sensor and parts of the sampling system are heated. And because the interlock even works perfectly at -40°C (during the Scandinavian winter, for example) and at 85°C (in blazing sunlight, for example), it was given the name "XT", for "eXtended Temperature".

Comparing different sensor systems

Besides interlocks with electrochemical sensors like the Dräger Interlock, devices equipped with semiconductor sensors are

Figure 4: Procedure for interlock use



1. Turn ignition key

2. Receive request to blow into Dräger Interlock

3. Measurement of the breath alcohol concentration

4. Breath sample accepted: motor starter released

5. Start engine

also available. Essentially, the semiconductor sensors have two disadvantages. Because of their lack of selectivity, other substances such as cigarette smoke, exhaust gases, petrol or acetone can produce a measurement result and, possibly, cause the starter to be blocked. Indeed, it has already been pointed out in many papers that interlock devices fitted with semiconductor sensors are extremely susceptible to interference [7, 8].

The second disadvantage concerns the long-term stability of the sensors. Devices with semiconductor sensors tend to require monthly calibration, while devices with an electrochemical measurement system can easily be used for six months before needing to be calibrated.
The lack of reliability of interlock devices with semiconductor sensors was one of the main reasons why use of the devices in the USA initially took a long time to become widespread, despite the necessary legal framework already being in place. The ICADTS report therefore expressly recommends the use of electrochemical sensors [2].

Effects of residual alcohol

If any residual alcohol or other substances in the mouth cause the starting motor to be blocked, a repeat breath sample can be given after a few minutes. During this period the driver must not smoke, drink or eat anything. After this time, it is certain that any residual substances will have been completely removed from the mouth and throat, so the test result can no longer be affected.

Approvals

In Europe, an interlock must be approved in accordance with the EC Directive on the suppression of radio interference in motor vehicles [9], which has been a condition for the installation of electrical devices in motor vehicles since 2002. In addition, as an independent "alcohol ignition interlock device", it also requires a "general type-approval" from the German Federal Bureau of Motor Vehicles and Drivers.

Requirements and standards for interlock devices are to be found worldwide: there is a European Standard [10], the requirements of the National Highway Traffic Safety Administration (NHTSA) in the USA [11], the Alberta requirements in Canada – introduced on account of the Province's extreme climatic conditions [12] – and the respective Australian standard [13].

Installation

To install the interlock, the voltage supply between the vehicle's ignition switch (position starter relay) and the starter relay is interrupted. This means that no voltage is supplied initially to the starter relay when the key is turned to the starter position, so no voltage is available to start the starter motor (Figure 5). The interlock is fitted into the interrupted lead with a relay that only releases the voltage supply to the starter system when a breath sample with a sufficiently low breath alcohol concentration has been given.
This installation procedure ensures that an interlock can only ever intervene in the engine starting process but can never influence a running engine, i.e. while the vehicle is moving. This is an important argument for the operational safety of the interlock.

Adjustable parameters

In the Dräger Interlock XT, authorized service centres can set a number of parameters using special software. The set values for the parameters, for example, can be defined by the authorities if the interlock is to be used in the area of driver licensing law.
In its default setting, the instrument does not display the measured breath alcohol concentration, but states merely whether the measured concentration is above or below the set limit value. This is designed to prevent a driver from using the interlock

to drink up to (but not exceed) the concentration limit.
For several minutes after the engine has been switched off, the vehicle can be started again without the need for a repeat breath sample. This is in the interests of road safety, allowing the vehicle to be started again immediately if the engine stalls in a critical situation or after brief stops.

To ensure that the driver remains under the legal limit even during longer journeys, interlocks can be set to request repeat breath samples at random intervals. Even if the breath sample is not successful, however, the running engine will not be stopped. Instead, the interlock's data log records that a breath sample has been refused or that the alcohol concentration measured was too high. This allows the data to be analysed subsequently and such incidents detected.

Data log and data record

While the vehicle is in use, all relevant incidents are recorded in the interlock's data log. The data recorded are the date, time, submission of or refusal to submit a breath sample, measured alcohol concentration, engine starts and stops, electrical bypassing of the interlock and any other attempts to tamper with the device.
If so desired, an authorized service centre, using special software, can download the data, compile a data record and then print

Figure 5: Installation circuit diagram of the Dräger Interlock XT

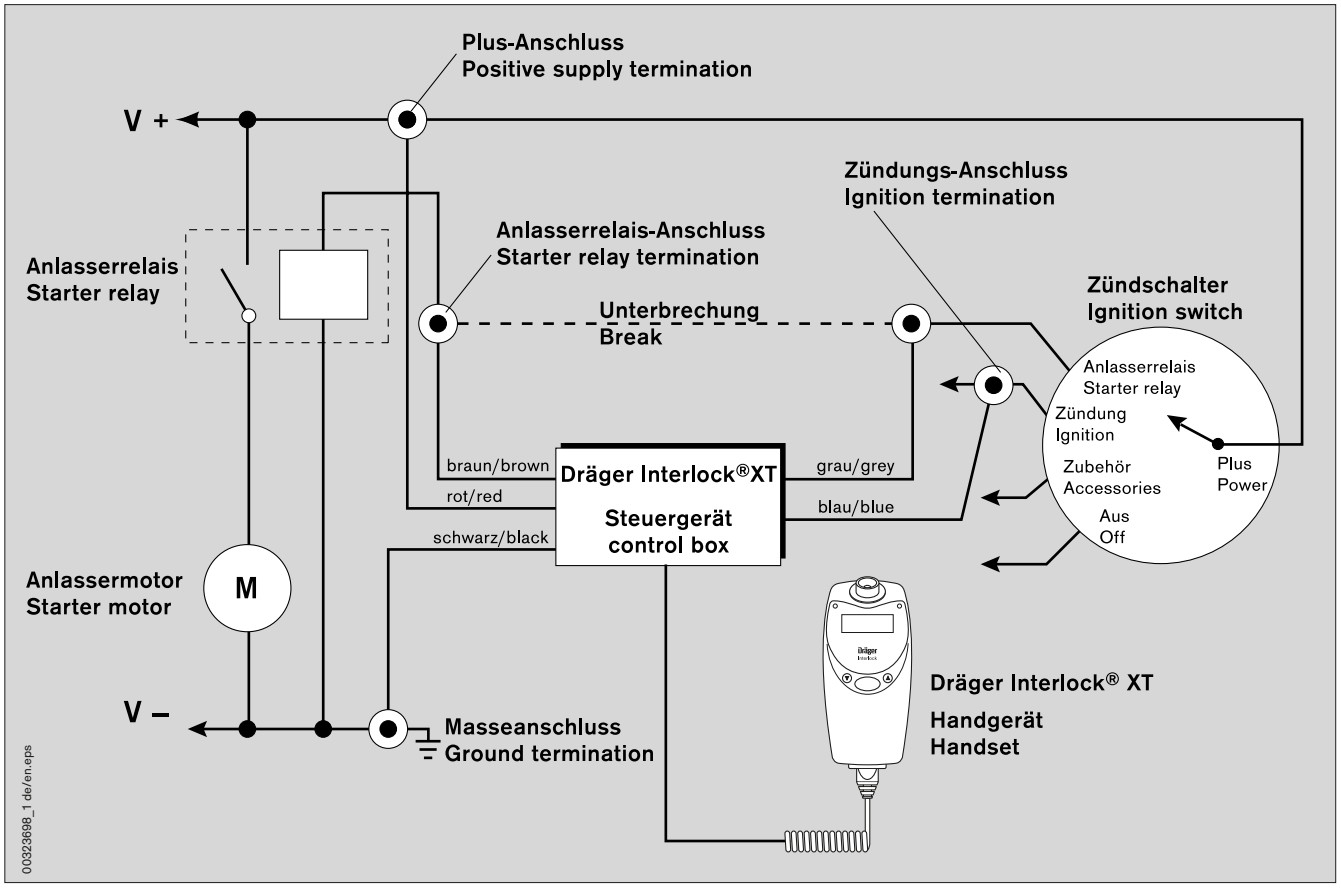


Figure 6: Use of an interlock in the transport industry

Figure 7: Preventive use of an interlock

it out. When the interlock is used in drink-driving offender programmes, this record can be sent to the driver vehicle licensing authority or other supervisory body for analysis, allowing proper use of the vehicle fitted with the interlock to be monitored.

The interlock system

When interlocks are introduced in a particular country, it is not only the device itself and its technical specifications which are important: how the devices are to be installed and regularly calibrated also needs to be clarified. A sufficiently dense network of service stations is necessary to allow calibration and, possibly, parameter setting, to ensure that a driver can reach a service station in a reasonable period of time. The stored data may also be downloaded at the service station and, if necessary, passed on to the supervisory authority.

Areas of application for interlocks

There are two distinct areas in which interlocks may be used: as a preventive measure or as ordered by a court as part of a drink-driving offender programme.
Installing an interlock as a preventive measure in transport vehicles such as hazardous goods transporters, lorries (Figure 6), coaches and taxis can reduce accident damage and downtime, improve the image of the transport company, and make customers feel safer. In private vehicles driven by persons with a possible or recognized alcohol problem, the voluntary installation of an interlock as a preventive measure can help the person to overcome their problem and can give considerable reassurance to partners (Figure 7) or to parents, for example, whose children also drive a car.
The second area in which interlocks are used is when a court or other authority orders an interlock to be installed in the vehicles of drivers who have a history of offences due to driving under the influence of alcohol. Discussions about this type of use have recently started in Europe, too, and in some European countries preparations are currently underway to change the laws accordingly – in Sweden and Finland this has already happened.

Arguments against the use of interlocks

Any discussion regarding interlocks should also take into account some of the arguments against their use. These include the costs of an interlock and, more importantly, the scope for tampering with and circumventing an interlock.
The costs of purchasing or renting and installing an interlock can initially be seen as an obstacle to deciding to use an interlock. This is without doubt a justified objection, especially in the case of people who are less well off. However, if we look at the costs of using an interlock, we soon realize that the sum is roughly equivalent to the cost of one or two glasses of schnapps per day. Indeed, if the interlock prompts a person who habitually drinks alcohol to reduce their consumption, it may even turn out to cost no extra.

The use of tools to circumvent the interlock, e.g. a pump or filter, will be detected by the Dräger Interlock XT and the engine prevented from starting. Any attempt to start the vehicle without first having given an acceptable breath sample is also recognized as tampering and recorded in the data log.

A commonly cited argument against interlocks is the possibility of a sober person providing a breath sample on behalf of a

drunk driver. Because of the specific way the breath sample has to be delivered, however, this person would have first had to practice how to do this. What is more, at least one sober person would have to be in the vehicle throughout the journey to provide acceptable breath samples whenever the repeat tests are activated. Finally, it is extremely unlikely that a sober person would knowingly provide a breath sample to enable a drunk driver to drive a vehicle. The simplest way to get around using the interlock is to drive a different vehicle in which no interlock is installed. However, if a person has been ordered to use an interlock as a condition for being permitted to drive, this is exactly the same as driving a vehicle without a driving licence. Obviously, as this is always possible even if a person has been banned from driving completely, an interlock cannot prevent it from happening.

Experience of interlocks [2], however, especially in the US, where interlocks have been used in large numbers for several years now, indicates that tampering is very rare and that it is given far more weight in theoretical discussions about interlocks than it actually happens in practice.

Conclusion

Today, state-of-the-art interlock devices like the Dräger Interlock XT are available: such devices are quickly ready for use even under extreme temperature conditions, prevent tampering and, thanks to the use of electrochemical sensors, offer long calibration intervals.

Installing an alcohol interlock is a reliable means of avoiding accidents caused by alcohol, as it can immediately separate alcohol consumption from driving. What is more, the interlock can support long-term behavioural changes with relation to alcohol consumption, thereby making an important contribution to improving road safety.

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Drug and alcohol testing in addiction prevention, treatment and medicine

Modern addiction prevention is a cross-functional task which involves tackling the multicausal problem of substance abuse on an interdisciplinary level, with pedagogical, psychological, medical and legal steps being taken in schools, in youth welfare programmes, by the police, by health insurance companies, in self-help groups and in medical professional associations [1].

To ensure an effective and sustainable programme of "prevention", a number of conditions have to be met. Among other things, these include ensuring the quality of addiction monitoring and treatment, concluding properly founded service agreements between treatment providers and health insurance companies, taking the often very specific local circumstances into account, and prerequisites as regards those taking part in the programmes.

The role played by substance monitoring in the form of drug testing is an important one, especially in drug substitution treatment and therapy following substance abuse. In the interests of quality assurance in this area, guidelines have been issued, regulations drawn up and processes described, demanding or recommending among other things the use of specific test procedures or equipment.

Substitution treatment

Dependence on drugs, and especially on opiates, is a chronic illness which requires treatment. The main objective of treatment is abstinence. The possible stages of a comprehensive treatment strategy are set down in the German Narcotic Drugs Prescription Order (BtMVV), § 5 Subsection 11 [2] and, on the basis of the generally recognized state of knowledge, by the German Medical Association in its guidelines for the substitution treatment of opiate addicts [3].

Substitution treatment ("methadone substitution") is only permissible when embedded within a comprehensive treatment programme. This includes among other things agreeing with the patients on the modalities of the planned treatment and explaining all the measures in detail. The patient must be taught about the substitution substance and its effects, possible interaction with other substances and how it affects a person's fitness to drive.

Monitoring concomitant substance abuse during substitution treatment

One essential aspect of treatment is substance monitoring (i.e. testing for drug or alcohol consumption). Drug tests carried out at the beginning of treatment to determine whether a person is still consuming opiates or other substances must be documented. "Monitoring of concomitant substance abuse", as it is known, is required by the German Narcotic Drugs Prescription Order (BtMVV) [2].

At the start of substitution treatment, close monitoring of any concomitant substance abuse is necessary. Unannounced, random testing must be carried out to determine whether there is concomitant use of other legal or illegal addictive substances, and to determine whether the substitute substance is being used properly. Testing is necessary to determine whether substances such as other opiates, cocaine, amphetamines/methamphetamines, benzodiazepines, methadone, cannabinoids, barbiturates or alcohol are being used concomitantly. If current concomitant use of other substances is detected, the substitution drug must be withheld if this could have a detrimental effect

Bild 1: Dräger Alcotest 7410 med in use

on health when taken in combination with the other substances. It is particularly important to remember that taking the substitute substance in combination with alcohol and/or sedatives could, in the worst case scenario, cause death.

This shows just how important it is to conduct alcohol and drug tests throughout the phases of diagnosis and treatment. The attending doctor has a duty to carefully document any concomitant use and to observe any considerations and consequences which this may entail. This documentation duty arises as a result of the existing employment law, the German Narcotic Drugs Prescription Order (BtMVV) and the particular requirements for substitution treatment of opiate addicts. Among other things, the frequency and results of tests for concomitant substance abuse must be recorded. These and all other measures must be documented and made available upon request in anonymous form to the competent Regional Medical Association, the competent Association of Statutory Health Insurance Physicians and/or the competent regional authority for the purposes of assessing the quality assurance measures. Modern drug and alcohol testing systems and procedures support and facilitate comprehensive documentation of concomitant abuse monitoring.

Quality assurance in substitution treatment

When providing a patient with substitution treatment, doctor's practices and outpatient clinics need to cooperate with numerous external partners (e.g. drug counsellors, providers of psychosocial support, other doctors, health insurance companies and social welfare providers, police, prisons and other authorities). It is essential to optimize this cooperation, e.g. with regard to information sharing. As a result, a central aspect of substitution treatment is the continuous quality management of the attending doctor, his representative or – if legally permitted – the pharmacist or other medical professional with the appropriate qualifications who is working on behalf of the doctor.
Among the measures undertaken to ensure the quality of substitution treatment are the following:

- creation of an individual control and treatment plan for each patient, containing the goals of treatment and when they are to be achieved, and monitoring progress and outcomes, and
- commitment to concomitant abuse monitoring (for alcohol, drugs and medication).

Quality assurance in outpatient substitution treatment programmes should attach particular importance to the conditions prevailing in the facilities themselves, e.g. the medical team, cooperation networks and space available. This also includes having the necessary equipment in terms of breath-alcohol and drug testing systems which conform to the legal requirements (e.g. MDD [4], IVD [5], German MPG [6]). Quality assurance also concerns how the facilities and their work processes are organized, i.e. arranging the daily handout of the substitute substances, carrying out monitoring for concomitant substance abuse and admitting new patients.

Monitoring for concomitant substance abuse

Monitoring a patient for concomitant substance abuse by means of an oral fluid or urine sample does not necessarily have to be performed by an external laboratory, as tests which can be carried out in any practice are readily available nowadays. There

are, however, significant differences in terms of quality and price between the available test kits.
The objective of a high-quality diagnostic analysis – including the procedure itself and its analytical value – is to take full and immediate account of each patient's individual circumstances. Bearing this in mind, test systems based on oral fluid samples offer a key advantage [7, 8, 9], as such methods of drug testing are able to add "quality" to the medical treatment process. This is because they are much more likely than the so-called "visually monitored urine samples" to meet the necessary medical (e.g. monitoring for concomitant abuse) and documentation requirements, and better reflect the patient's own – often subjective – capabilities.

What is more, there is no need for the laborious steps aimed at preventing adulteration and manipulation which have to be performed during urine testing. The fact that equipment is purchased to electronically measure the urine temperature, or that CCTV systems are installed in toilets, or that patients are requested to undress completely before visiting the toilet, serves to illustrate just what sort of difficulties drug testing can involve. Many doctors prefer not to use such measures, and seek instead to build up a doctor-patient relationship which is not founded on excessive mistrust. In this context, oral fluid-based drug testing can act as a "bridge" and help to generate trust, as a sample can be provided anytime and anywhere, without having to violate a patient's private sphere [10].

When it comes to monitoring for the concomitant consumption of alcohol, high-quality electronic breath-alcohol detectors, preferably with electrochemical sensor systems, should be used to meet the requirements for quality assurance in substitution treatment [11].

Who pays for the concomitant substance abuse monitoring during substitution treatment?

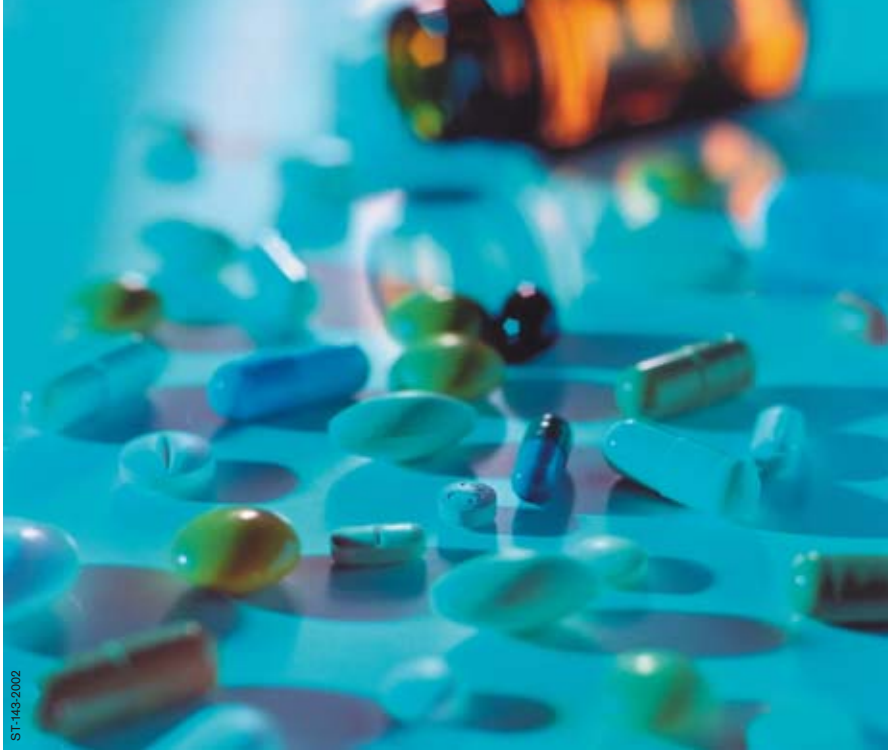
Because the guidelines issued by the German Medical Council (Bundesärztekammer - BÄK) [3] expressly state the necessity for breath-alcohol monitoring, breath-alcohol testing was included in 2003 in the "assessment standard for services provided by a doctor (BMÄ)“ [11]. Since then, determining alcohol in a person's exhaled air within the framework of substitution treatment can be charged to the Compulsory Health Insurance (Gesetzliche Krankenversicherung - GKV) at a rate of currently 1 EUR. At the same time, the highest rates for drug testing within the framework of substitution treatment are currently around 3 EUR per substance and/or group of substances [12].
The number of drug measurements which can be performed for patients who undergo substitution treatment in accordance with the guidelines of the Federal Association of Physicians and Health Insurance Organizations and whose treatment is paid for by Compulsory Health Insurance is limited. At the present time, up to 125 EUR can be charged in the first two quarters of treatment, and 64 EUR per quarter from the third quarter on. As a rule, much the same applies for patients whose substitution treatment is paid for by a social welfare provider, who normally base their practices on those of the Compulsory Health Insurance.

Medical devices and CE marking

In the European Union, the requirements for products and devices used for medical purposes are set out mainly in two European Directives. EU Directive 93/42/EEC deals with medical devices (MDD Directive) [4], while EU Directive 98/79/EC deals with in vitro diagnostic medical devices (IVD Directive) [5] (in vitro = in a test tube). Both Directives were transposed together into national law in Germany in the form of the Medical Devices Act (MPG) [6].
If products comply with one of the two directives, they are CE marked (and possibly marked with the ID number of the notified body) and the manufacturer issues a declaration of conformity. This serves as documentation that all the relevant requirements of the EU Directives have been met. These requirements may also demand a special quality assurance system, including auditing by an external body.
Once the product has been reported to the competent authority, the product with the CE mark can be placed on the market. In addition, the company responsible for the product creates a product file to allow all information relevant to the product to be recorded and made available at any time. The manufacturer of the product is also required to establish and maintain a systematic procedure to provide information about incidents which could result or have resulted in the death or serious harm to health of a patient or user.

Does drug testing equipment classify as medical devices?

Deciding whether drug testing procedures fall within the scope of the in vitro diagnostic medical devices directive of the European Union (IVD Directive) [5] or in Germany within the scope of the Medical Devices Act (MPG) [6] depends on what they are used for.
The IVD defines an in vitro diagnostic medical device as follows:
“An in vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, ..., intended by the manufacturer to be used in vitro for the examination of specimens, ..., derived from the human body, solely or principally for the purpose of providing information:
– concerning a physiological or pathological state, or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– concerning a congenital abnormality, or
– to determine the safety and compatibility with potential recipients, or
– to monitor therapeutic measures."

Drug testing procedures in the domain of substance abuse are used – especially in substitution treatment and therapy – to determine whether patients are consuming other drugs besides the substitute. Furthermore, the patient is monitored to check that the substitute itself is being taken correctly. In other words, this application corresponds to the definition of in vitro diagnostic medical devices contained in the MPG, and as such, devices and monitoring systems used for these purposes must meet the relevant legal requirements for in vitro diagnostic medical devices.

Do breath-alcohol measuring instruments fall within the scope of the Medical Devices Directive and the German Medical Devices Operator Ordinance?

Deciding whether breath-alcohol measuring instruments fall within the scope of the Medical Devices Directive of the European Union (MDD) [4] or in Germany within the scope of the Medical Devices Act (MPG) [6] and the Medical Devices Operator Ordinance (MPBetrV) [13] depends on what they are used for.

The MDD defines a medical device as follows:

"An medical device means any instrument, apparatus, ... , whether used alone or in combination, ... intended by the manufacturer to be used for human beings for the purpose of:

– diagnosis, prevention, monitoring, treatment or alleviation of disease,
– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
– investigation, replacement or modification of the anatomy or of a physiological process,
– control of conception, ..."

Based on this definition of a medical device within the meaning of the relevant legal regulations a decision can be taken for individual applications – as shown below – as to whether breath-alcohol measuring instruments fall within the scope of the respective regulations. In individual cases, however, the manufacturer cannot ultimately decide which alcotest device is allowed to be used for which application and with which regulations it must therefore comply. This decision must be taken by users themselves.

Breath-alcohol measuring instruments in substitution treatment

The German Narcotic Drugs Prescription Order (BtMVV) states the following in § 5 [2]: "(2) ... Prescribing a substitute substance is permissible if and for as long as the investigations undertaken by the doctor do not indicate that the patient ... c) is using substances whose consumption, depending on type and quantity, could endanger the purpose of the substitution. ...
(9) The doctor shall document the completion of the measures required in the preceding sections. The documentation shall be presented or sent in to the competent regional authority upon request for inspection and assessment."

Furthermore, the guidelines issued by the German Medical Council for the substitution treatment of opiate addicts [3] state the following in Subsection 11 (monitoring treatment / concomitant substance abuse): "Monitoring of concomitant substance abuse is required by the BtMVV. ... In this context, the concomitant abuse of other opiates, and also of benzodiazepines, cocaine, amphetamines and alcohol – depending on the circumstances of the individual case – should be checked. ... The substitute substance must not be issued if recent concomitant substance abuse is detected such as would damage the patient's health if the substitute were additionally administered. In particular, it should be noted that taking the substitute in combination with alcohol and/or sedatives can result in respiratory depression and death. ... The attending doctor has a duty to carefully document any concomitant substance abuse and the considerations and consequences resulting from this. ... "

According to the above, breath-alcohol testing during substitution treatment is intended to "prevent disease", meaning that the devices fall within the scope of the MDD, and must have the necessary approval.

Breath-alcohol measuring instruments during operations and medical emergencies

Breath-alcohol measurements are often conducted during surgical operations. The breath-alcohol measuring instrument is used to diagnose vascular injuries, e.g. during transurethral resection of prostate in urology (TUR-P) [14] or transcervical resection of the endometrium in gynaecology (TCRE). If an ethanol-based irrigation solution is applied prior to this type of surgery, the ethanol will be quickly detectable in the patient's exhaled air in the event of a vascular injury.
When a breath-alcohol measuring instrument is used to prevent absorption of irrigation solutions during surgery, this is done with a view to "diagnose injuries and preventing disease".

The same applies equally to breath-alcohol measurements carried out during medical emergencies and in the A&E department of a hospital in order to determine whether a person requiring emergency treatment who may not be responsive is under the influence of alcohol or suffering from some other condition. Here too, the measurement is conducted to "diagnose injuries and prevent disease".
Such applications, carried out during operations and medical emergencies or in the A&E department, clearly fall within the scope of the MDD, and the breath-alcohol measuring instruments must therefore have the relevant medical device approval.

Breath-alcohol measuring instruments in addiction and detox clinics

If a patient who is not undergoing substitution treatment is tested in a clinic (an addiction or detox clinic, for example) to determine whether he or she has infringed regulations by consuming alcohol, this is not done for the purposes of "diagnosis, prevention, monitoring, treatment or alleviation of disease", and also does not correspond to any of the other intended purposes listed. Just as when the devices are used by the police, this procedure is performed simply to determine whether a person has consumed alcohol and, in doing so, has violated the applicable laws or regulations.
For these applications, then, it is not essential for a breath-alcohol measuring instrument to be approved in accordance with the MDD.
However, since addiction and detox clinics often also employ breath-alcohol measurements to monitor concomitant substance abuse during substitution treatment, it is recommended that breath-alcohol measuring instruments with the relevant medical device approval should be used when testing for "compliance with regulations".

Functionality and safety checks

The use of medical devices requires regular testing of their proper function and, in the case of measuring instruments, of correct calibration, as otherwise the risk of harming the patient would be too great and not acceptable.
The German Medical Devices Operator Ordinance [13] states the following: "The user shall check the function and proper condition of the medical device prior to use." This can be done by conducting a simple functional test, for example.

In addition, safety inspections must be carried out at certain intervals [13]: "In the case of medical devices for which the manufacturer has prescribed safety inspections, the operator shall perform these inspections, or have them performed, in accordance with the manufacturer's instructions and the generally recognized rules of technology, and within the intervals stated by the manufacturer. The safety inspections include testing of the measurement function. A record shall be made of the safety inspection."
Determining functionality and conducting safety inspections constitutes another part of quality assurance.

Dräger Alcotest devices with medical device approval

As part of the Dräger Alcotest family [15, 16], which has been widely used for many years, the Alcotest 7410 med (Figure 1) and Alcotest 6810 med (Figure 2) models were developed. These are specially designed for use as medical devices and bear the respective CE mark in accordance with EU Directive 93/42/EEC for medical devices [4]. Besides the high quality and proven reliability of the electrochemical DrägerSensor, the devices boast a number of features which facilitate routine medical use.
The devices of the Alcotest med series are specifically designed for determining the breath-alcohol concentration in medical applications. For example, they can be used to diagnose vascular injuries (during transurethral resection of prostate in urology, for instance) following prior application of an ethanol-based irrigation solution. They are also suitable for testing patients for prior alcohol consumption in the A&E department or before methadone substitution.
The electrochemical DrägerSensor, which offers fast response times and long-term stability, is ready for the first measurement soon after power up, rapidly analyses the measurement signal, and boasts a low standard deviation. The device's illuminated display screen (which contains information such as the test number, date, time, measurement result and error messages), the colour LEDs and the audible signal guide the user smoothly through operation of the device.
During the automatic measurement which is triggered when a breath sample is given, the respiratory flow is measured and the minimum volume adjusted such as to ensure that air from deep inside the lungs is sampled. The manual measurement option

allows the device to be used even on people who are unconscious, anaesthetized or not responsive for any other reason and are therefore unable to consciously provide a breath sample.

The integrated data log in the breath-alcohol detectors can store around 8,000 sets of data for personal measurement results. The data interface allows the results to be transferred to a PC once the measurement has been completed, ensuring continuous documentation during, for example, medical treatment or substitution treatment as part of a drug therapy programme.
To ensure before use that the devices are functioning properly, a self-test is performed when the devices are switched on. This, combined with a straightforward check of measurement function (which should be performed once a week), guarantees the quality of measurement. In addition, a six-monthly safety inspection, also encompassing the measurement function, is to be carried out in accordance with the German Medical Devices Operator Ordinance.
Apart from the breath-alcohol measuring instruments themselves, the special mouthpieces which are used with them also count as medical devices. Other accessories such as the documentation software, charger and transport case, however, are not classified as medical devices.
Dräger Alcotest med devices are medical devices which should be used for systematic quality management in every doctor's practice, outpatient facility and clinic to ensure safe and error-free processes. They support the organization of operating processes and the documentation systems required by the legal regulations for medical devices.

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Figure 2: Dräger Alcotest 6810 med

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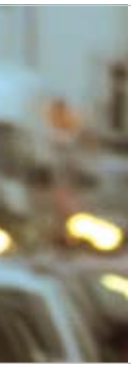

Possible approaches to road safety

Worldwide, around one million people die every year as a result of traffic accidents, and another ten million are injured. On Europe's roads alone, more than 40,000 people are killed every year and 1.7 million are injured, some of them remaining dis abled for the rest of their lives. The estimated direct and indirect financial costs in Europe total more than 160 billion euros a year [1].

Because of the severity of the accidents it causes, driving under the influence of alcohol and/or drugs is one of the biggest problems on our roads. However, road users under the influence of "other intoxicating substances", i.e. illicit drugs or medication, are not easily detected by routine roadside police checks, and are therefore only reflected in the accident statistics to a limited extent. All the same, the number of registered traffic accidents involving a driver who has been proven to be under the influence of drugs or medication has risen constantly during the course of recent years. In Germany, for example, 1,457 accidents involving personal injury and a driver under the influence of "other intoxicating substances" were registered in 2004, and 51 accidents resulted in fatalities. In addition, 842 serious accidents involving damage to property were recorded [2]. What is more, there is also thought to be a very high number of unrecorded cases, as drug detection is subject to a complex and sophisticated classification process. Research into the real number of cases indicates that only one in at least 1,000 drivers under the influence of drugs is caught [3]. It is not as easy to tell whether someone is under the influence of drugs as is the case with alcohol (e.g. from the typical smell of alcohol).

Medical and illegal drugs on the roads – the legal situation

Laws relating to "medical and illegal drugs on the roads" differ from country to country. Generally speaking, proof of a person's unfitness to drive is required in all countries to allow them to be prosecuted for driving under the influence of alcohol or "other intoxicating substances" ("impairment law"). In addition, some countries (such as Germany, Belgium, Sweden France and Finland) have adopted other laws which do not depend on proof of influence; mere toxicological evidence of an intoxicating substance is sufficient to impose a legal penalty ("zero tolerance").

In June 2003, the European Legal Database on Drugs (ELDD) published a comparative study of the legal situation relating to "Drugs and Driving" in 16 countries. It was found that although driving under the influence of drugs constitutes an offence in all countries, there are considerable differences regarding the rights of the police to test drivers, the substances consumed and the applicable legal penalties [4].

The legislative and executive situation in a number of countries (in alphabetical order) is described below.

Australia

Under the "Road Transport (Alcohol and Drugs) Act 1977", it is prohibited in all states of Australia to drive a motor vehicle under the influence of intoxicating substances (listed in the Act).

Until recently, no Australian states had laws allowing random drug testing. Reasonable suspicion was necessary to demand a blood or urine sample. In reality, this only ever happened once a driver had already been involved in an accident.

As a result of toxicological studies which in 2001 showed 29.3 percent of drivers killed in road traffic accidents to have "other in-

toxicating substances" in their blood (in 16.5 percent, THC and/or stimulants were specifically detected) [5], a fundamental decision was taken when the "Road Safety (Drug Driving) Act 2003" was amended in the state of Victoria in December 2003. The change in the law allows police to conduct random roadside testing of drivers, with oral fluid screening tests being used to detect exclusively THC and designer amphetamines; THC is the drug most commonly found (after alcohol) in fatally injured drivers in Victoria, and methamphetamine is the most commonly found drug in lorry drivers killed in Victoria.

In February 2004, tenders were publicly invited for oral fluid-based screening systems, and various systems were tested for possible suitability. The testing programme covered not only trials with synthetic samples in the laboratory, but also testing of volunteers in controlled clinical studies and testing under controlled conditions at the workplace. An acceptable test system needed to offer a high level of specificity in order to spare the drivers tested (the majority of whom tested negatively) the unpleasantness of a false-positive result. Great importance was attached to minimizing potential risks and to improving road safety.

The new regulation came into force in Victoria on 1 July 2005. Under the new legislation, oral fluid laboratory analysis has been approved as "evidential", i.e. admissible as evidence in a court of law. Offenders can face anything from a fine of around 175 euros to a fine of some 700 euros plus a six-month ban [6].

A law has also been in force in Tasmania since July 2005 which allows random roadside drug testing of motor vehicle drivers without any prior suspicion. The programmes in Victoria and Tasmania serve as pilot projects, and no such legal initiatives exist (as yet) in the other states of Australia.

Austria

Under the Austrian Road Traffic Act (StVO) of 1960, "drivers impaired by narcotic drugs“ who are not able to drive a vehicle safely are not permitted to drive or start a motor vehicle. An official doctor determines whether the driver is impaired, and in the case of a positive test result arranges for a blood sample.

In the case of impairment which is not obviously due to drugs, oral fluid-based screening test devices can be used under the 21st amendment of the StVO. The amendment came into force on 1 July 2005 and states explicitly that no screening tests may be performed where there is a clear suspicion of drug influence; in such cases the driver must be presented to an official doctor. If an oral fluid test shows a positive result, a medical examination is conducted whose result will determine what happens next.

The Interior Minister determines by decree which oral fluid screening tests can be used. At the present time, various methods are being investigated by a study commissioned by the Federal Transport Minister.

Belgium

Laws which make driving under the influence of drugs an offence have been in place in Belgium for many years.

In response to the results of the "Belgian Toxicology and Trauma Study" [7], which found evidence of drugs in 19 percent of injured drivers, the law in Belgium was changed in March 1999. As a result, it is now forbidden to drive a motor vehicle if toxicological evidence of intoxicating substances can be found in the driver's blood.

Although an initial suspicion is needed, the law takes effect even without any concrete evidence of the influence. The following substances and detection limits (in the blood plasma) are covered by the law: amphetamine (50 ng/ml), the designer drugs MDMA, MDEA, MBDB (50 ng/ml each), THC (2 ng/ml), cocaine or benzoylecgonine (50 ng/ml), and free morphine (20 ng/ml).
Roadside drug testing takes place in three stages:

– observation of external signs which arouse suspicion that the driver is under the influence of one of the defined substances (standardized recognition procedure),
– taking of a urine sample which is checked using a urine screening test for drugs,
– medical examination and blood sample.

The use of oral fluid as a screening test material is currently being tested as part of the ROSITA-2 project [8]. An internal survey of police officers indicates that oral fluid is given clear preference over urine as sample material.

Finland

Under the revised version of Chapter 23 of the Penal Code, any driver of a motor vehilce whose blood is found to contain "an active narcotic substance or its metabolite" will be charged with drinking while intoxicated, except in such cases where the substances were prescribed by a doctor.
If, however, it can be proven that a person's fitness to drive is impaired, the driver will be charged with drinking while intoxicated regardless of whether the substance was prescribed by a doctor or not.

France

In 1999, an article was incorporated into the existing legislation in France to demand a systematic search for drugs as the possible cause of fatal road traffic accidents.
Since it proved insufficient to restrict the search to fatal accidents, the law was extended to generally include "driving under the influence of substances or plants classed as narcotics“ (law no. 2003-7 of 3 Feb. 2003). Now, if evidence of consciousness-changing substances is found in the blood, this automatically constitutes an offence which will have legal consequences. There are no specified limits.
According to the law, all drivers involved in a fatal road traffic accident must now be tested, as must drivers involved in a road traffic accident involving personal damage where there are reasonable grounds to suspect the consumption of drugs. Furthermore, facultative testing can be carried out following general road traffic accidents or other offences.
Drug screening tests can be used by medically trained personnel as an additional aid. A urine sample can only be taken in hospitals, emergency wards or the surgery of the doctor asked to take the sample. By the end of 2005, the police should have been supplied with the first oral fluid-based drug screening tests. If a person tests positively, a medical examination and blood sample are necessary.

Germany

Driving under the influence of alcohol and "other intoxicating substances" is treated as an offence in Germany and is punishable under § 316 of the German Criminal Code, StGB, or under § 315c StGB ("endangering road traffic"). No specific endangering of road traffic or erratic driving is necessary for a punishment to be imposed in accordance with § 316 StGB, though a person's unfitness to drive must be proved. Since too little data is available (as yet) regarding the link between the concentrations of active substances and a person's ability to

List of intoxicating substances and substances to be detected as specified in the annex to § 24a StVG.

Intoxicating substance	Substance to be detected
Cannabis	Tetrahydrocannabinol (THC)
Heroin	Morphine
Morphine	Morphine
Cocaine	Benzoylecgonine
Amphetamine	Amphetamine
Designer amphetamines	MDMA, MDEA

drive, no specified limits exist for the "other intoxicating substances" which, if exceeded, would constitute evidence of a person's complete unfitness to drive – in contrast to alcohol, for which the limit is 1.1 ‰. As a result, besides relevant analytical evidence, the driver must be found to exhibit behavioural disorders caused by drugs. Impairment can be determined on the basis of vegetative symptoms (e.g. size and reaction of pupils), coordination problems (including difficulties with walking and other tests of coordination) or noticeable psychological effects (e.g. a mental slowness or inability to concentrate, with thoughts wandering). Several such symptoms must be in evidence to prove a person's unfitness to drive, although one single but very pronounced symptom can also suffice. A laboratory reading alone, regardless of how high the detected concentration(s) may be, is not enough to prove a person's unfitness to drive.
The blood sample taken is examined for the presence of "other intoxicating substances" and a toxicological report is compiled. If this shows evidence of impairment, and a court comes to the same conclusion in view of the documented behavioural disorders, the offender's driving licence will be withdrawn. An application for a new licence cannot be made until the driving ban has elapsed (usually 6 to 12 months).
Under § 315c StGB, the punishment will be more severe if a person who is unfit to drive due to the consumption of "other intoxicating substances" has actually caused danger to life, limb or property of significant value.

The lack of specified thresholds to describe total unfitness to drive makes it relatively difficult to successfully prosecute drug-driving in practice.
Sanctioning of driving under the influence of drugs became considerably easier following amendment of § 24a of the Road Traffic Code, StVG, as of 1 August 1998, which serves as an important complement to the existing criminal laws. Under Subsection 2, a person driving a motor vehicle on a public road under the influence of an intoxicating substance is now guilty of an administrative offence. This is assumed to be the case if analytical evidence of the active substance or its decomposition product is found in the person's blood.
The intoxicating substances to which this provision applies are not specified in the law, but are listed in a separate annex, which can be extended by executive order to include further substances if current scientific knowledge deems this necessary for the sake of road traffic safety and if reliable toxicological evidence can be provided.

The substances listed can only be detected in the blood for a short period of time after consumption, so police officers need to watch for symptoms such as red eyes, slow pupil reactions etc. which are indicative of recent consumption. These initial observations can then be corroborated using drug screening tests. A blood sample is ordered and analysed for confirmation purposes in a laboratory. If the blood sample tests positive for one of the substances listed in the annex to § 24a StVG, a driving ban of up to one month and a fine can be imposed.
Since at the present time analytical evidence in the blood is the only thing that constitutes an offence, § 24a (2) StVG redresses the problem of there being a lack of penalties for instances of drug-driving without consequences – in other words, situations in which it is not possible to prove conclusively that a person is unfit to drive within the meaning of §§ 316/315c StGB. As such, the administrative regulation can be seen

as a "catch-all element" which complements the criminal law regulations with correspondingly lower legal consequences. The introduction of analytical thresholds to ensure some degree of correspondence between the duration of effect and detection is currently under discussion.

Italy

Under Article 187 of law 285/1992 in Italy, it is "... prohibited to drive a vehicle in an altered physical or mental condition resulting from the use of narcotic or psychotropic substances". If road traffic police officers suspect a driver to be under the influence, they have the right under Article 12, Sections 1 and 2 to accompany the person in question to a mobile or fixed sanitary facility for the purposes of conducting a screening test or taking a blood sample.

Netherlands

According to Article 8 of the Dutch Road Traffic Law, drivers are not permitted to drive a motor vehicle under the influence "of a substance whose use – either on its own or in combination with another substance – they know or should reasonably know to be capable of impairing a person's ability to drive". No analytical limits are specified by the law.

Legal proof that the driver is under the influence of intoxicating substances other than alcohol must be provided by detecting a substance potentially able to influence driving ability in the blood or urine, by proving intention, and by demonstrating a link between the detected substance and the effect which was actually brought about. At the present time, the inclusion of specified limit values for "other intoxicating substances" in the existing legislation is under discussion. This would require the use of reliable screening test equipment, preferably based on an oral fluid sample obtained on site.

Spain

Police in Spain can conduct drug testing at any time, even without any initial suspicion. Like in the German laws, analytical evidence of drugs in the driver's blood is enough to constitute an administrative offence. No specific limits exist, as the "zero tolerance" principle applies.
For a person to be guilty of an offence, Article 379 of the Spanish Criminal Code requires evidence of influence.

Sweden

On 1 July 1999, a new provision for driving under the influence "of other intoxicating substances" was included in the Swedish Road Traffic Offences Act. Drivers are prosecuted who are found to have toxicological evidence of narcotics and benzodiazepines exceeding specified limits in their blood.

Switzerland

As of 1 January 2005, a zero limit came into force for certain drugs in Switzerland. Under Article 2, Subsection 2 of the Road Traffic Ordinance (VRV), a person is deemed unfit to drive when certain substances are found in their blood. Although the police still cannot conduct drug testing without any reason – unlike with alcohol – a road user can be subjected to a drug screening test if he or she is found to be impaired due to the influence of narcotics and/or pharmaceuticals. If the result of the test is positive, a blood sample, a medical examination and a chemical toxicological analysis are ordered.
According to ASTRA, the Swiss Federal Roads Authority, a person is regarded as unfit to drive if there is evidence of at least 1.5 ng/ml of THC in their whole blood or a concentration of at least 15 ng/ml of cocaine, free morphine, amphetamine, methamphetamine, MDMA and/or MDEA in their whole blood. There is no need to prove any effect. On the basis of the results of the examinations, sanctions are imposed under criminal or administrative law.

United Kingdom

Under Section 3A/4 of the Road Traffic Act from 1988, a person is guilty of an offence if he or she drives or attempts to drive a motor vehicle under the influence of "other intoxicating substances".
To provide a legal basis for how to recognize drivers under the influence, the new "UK Railways and Transport Safety Act" from 2003 gives an officer on site the authority to order drug screening tests. The sample material is not explicitly stated.

The legal situation in the USA

Laws governing how to recognize motor vehicle drivers under the influence of drugs vary greatly from state to state in the US, with no uniform country-wide regulation in place. In the majority of cases, the provisions are to be found in the transport or motor vehicle laws of the individual states, while in three states they are contained in the penal code. A detailed overview is provided by the "Walshgroup" and the "Robert Wood Johnson Foundation" [9].
In accordance with the laws, prosecution of offenders in most states requires proof that the consumed substance/s is/are responsible for the impaired ability to drive. In eight states (Arizona, Georgia, Iowa, Indiana, Illinois, Michigan, Rhode Island, Utah) a "per se" regulation is in force under which evidence of an intoxicating substance in the driver's blood or urine is sufficient. Eight other states also have "per se" regulations, though these do not necessarily require proof of intoxicating substances in the body. While only blood testing is permitted in Texas and Maryland, blood and urine testing is possible in the majority of states (40). Five states (Colorado, Montana, New York, North Dakota, Oklahoma) explicitly permit oral fluid testing besides blood and urine, while other human sample material

besides blood and urine is admissible in eight other states. Three states do not permit testing of any human material at all. Immunological screening tests are not routinely used by police in any states at the present time.

The ROSITA and ROSITA 2 projects

From January 1999 to September 2000, different methods of screen testing for drug effects were assessed as part of the ROSITA [10] project to determine their possibilities and limitations for use by police in traffic monitoring. During the course of this EU research project, drug screening tests were carried out throughout Europe on nearly 3,000 persons suspected to be under the influence of drugs.

The results indicate that the targeted use of drug screening devices offers the police important advantages:

- they provide immediate confirmation of an initial suspicion, thereby rapidly boosting the confidence of police officers as regards recognizing the effects of drugs as exhibited by road users
- the use of screening test devices reduces the number of unjustified blood samples
- the per case costs for police are greatly reduced.

From an analytical point of view, it is particularly important to minimize incorrect results (false-negative or false-positive). Drivers who test false-negatively pose a potential threat to road traffic safety, while false-positive results generate unnecssary costs, reduce confidence in the measurement technology and harm the reputation (and authority) of those conducting the tests at the roadside.

Furthermore, it can be assumed from the data collected during the studies that the drop in the number of road traffic accidents and the reduction in the number of those killed and injured in such accidents can be attributed to the roadside drug screening

Overview of the laws in European countries governing driving under the influence of "other intoxicating substances". [12]

Country	Type	Administrative / Criminal	Fine (€)	Prison	Licence withdrawal
Austria	Impairment	Administrative	581 – 3633		1 months
Belgium	“Per se”	Criminal	1000 – 10000	15 – 180 days	Possible
	Impairment	Criminal	1000 – 10000	15 – 180 days	Possible
Denmark	Impairment	Criminal	Fine	365 days	
Finland	“Per se”	Criminal	Fine	182 days	Max 60 months
	Impairment	Criminal	60 day fines	700 days	Max 60 months
France	“Per se”	Criminal	4500	730 days	36 months
Germany	“Per se”	Administrative	250		1 months
	Impairment	Criminal	Fine	365 days	Withdrawal
Greece	Impairment	Criminal	147	60 days	3 – 6 months
Ireland	Impairment	Criminal	1270	180 days	24 months
Italy	Impairment	Criminal	260 – 1030	30 days	0,5 – 3 months
Luxembourg	Impairment	Criminal	250 – 5000	8 – 1095 days	Possible
Netherlands	Impairment	Criminal	Accident: 11250	1095 days	60 months
	Impairment	Criminal	Fatal: 45000	3285 days	60 months
Norway	Impairment	Criminal		365 days	12 months
Portugal	Impairment	Criminal	360 – 1800	365 days	2 – 24 months
Spain	“Per se”	Administrative	302 – 602	8 – 12 weeks	3 months
	Impairment	Criminal	302 – 602	8 – 12 weeks	12 – 48 months
Sweden	“Per se”	Criminal	Day fines	730 days	1 – 36 months
United Kingdom	Impairment	Criminal	7000	180 days	At least 12 month

tests conducted by police as part of the ROSITA project [11].
There is a clear need for police to be equipped with drug screening test systems to help them identify drivers under the influence of drugs. Police throughout the German state of Saarland, for example, were equipped with drug screening tests in 2001 following a decision taken by the Saarland Interior Ministry. The pattern of drug consumption among road users as identified by the ROSITA project shows clearly that the reliable detection of cannabis and amphetamines and designer drugs by drug screening tests is currently the most important aspect of identifying drivers under the influence of drugs.
The project has resulted in action being taken not only in Germany, and has also been watched with international interest, with road traffic policy changing in several European countries as a result. For this reason, the research partners which participated in ROSITA have been asked by the EU to take part in a follow-up project. This follow-up project, known as "ROSITA 2", has been approved by the European Commission [8]. Besides German participation, partner institutions from Spain, Belgium, France, Finland and Norway are involved, as are the National Institute on Drug Abuse and the National Traffic Highway Safety Administration (NTHSA) from the USA. The main focus of the project's studies is to examine the usefulness for police of screening test systems based solely on oral fluid; urine screening test devices will not be covered by the field study. The project will be completed by the end of 2006, and the results then published.

Discussion

In today's society, drug-related road traffic offences are being treated increasingly seriously. This trend is reflected in more and more countries around the world, which have been continuously updating their laws over the past few years to ensure that drivers under the influence of "other intoxicating substances" can be identified more easily, quickly and reliably, and to directly prevent such persons from driving.
The use of drug screening tests has already started to be incorporated into some of the respective laws. Such tests are excellent diagnostic detection instruments which allow a person's consumption of drugs and/or current state of drug influence to be quickly and easily determined and – depending on the particular situation – to clarify whether or not they are "fit to drive". Although police officers who are practised in recognizing drug users can generally determine whether a person is acting dangerously or strangely as a result of drugs, the topic of "drugs on the roads" is still unfamiliar ground to the majority of police officers. Such officers are often uncertain whether it is enough for a person to be demonstrating unusual mental or physical behaviour for this to be attributed to the effects of drugs and for them to initiate the relevant legal steps.
However, it should always be remembered that immunochemical drug screening tests, regardless of their quality and possible applications, are just one of several of the mosaics which form the basis for a police officer having grounds for suspicion. Ultimately, especially under German law, other unambiguous signs are necessary (strange behaviour, slow pupil reactions etc.) before a driver can be suspected of consumption of one or more drugs. A positive screening test cannot and should not be used as the sole reason for taking a blood sample due to the fact that courts require the results to be corroborated by a "conclusive and consistent overall impression of impairment" before they can be admitted as reliable evidence. Analytically speaking, too, particular attention must be paid to how the results of immunological drug testing procedures are interpreted. In the case of a "non-negative" result, the screening test material or – depending on the particular

circumstances and legal situation – other bodily materials (oral fluid, blood, urine, keratin fibres) must be subjected to a confirmation analysis using a recognized method of measurement (e.g. GC-MS, LC-MS, GC-MSMS or similar) to allow the appropriate legal action to be taken on a completely dependable analytical basis.

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