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## 1 For your safety

### 1.1 Strictly follow the Instructions for Use

Any use of the Dräger DrugTest 5000 Analyzer and of the Dräger DrugTest 5000 test kits requires full understanding and strict observation of their respective instructions for use. Failure to do so can lead to incorrect measurement results or damage the unit.

The Dräger DrugTest 5000 Analyzer and the Dräger DrugTest 5000 Test Kit are only to be used as described.

### 1.2 Maintenance

The device must be inspected and serviced regularly by specialists.

Repairs and maintenance to the device may only be carried out by trained service personnel.

We recommend taking out a service contract with Dräger and having all repairs carried out by Dräger.

Only authentic Dräger parts may be used for maintenance.

The Dräger DrugTest 5000 Analyzer does not contain any user-serviceable parts. Unauthorized opening of the unit makes any claims under guarantee void.

Annual inspections of the unit are recommended. See "Maintenance intervals" on page 48.

#### 1.2.1 Not for use in areas of explosion hazard

The unit is not approved for operation in areas prone to explosion.

#### 1.2.2 Coupling with other electrical units

Units not mentioned in this technical manual may only be electrically coupled after prior consultation with Dräger.

#### 1.2.3 Reaction to damage in transit

If the unit arrives in damaged condition, you should immediately request a check by the shipping company and the local service representative.

Dräger is not responsible for any damage caused during transport, but it will however assist in clarifying the incident with the carrier in question.

### 1.3 Warning messages

This technical Manual uses the following warnings for risks and hazards which might occur when using the unit.



#### CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in physical injury, damage to property or damage to the environment. It may also be used to alert against unsafe practices.



#### NOTICE

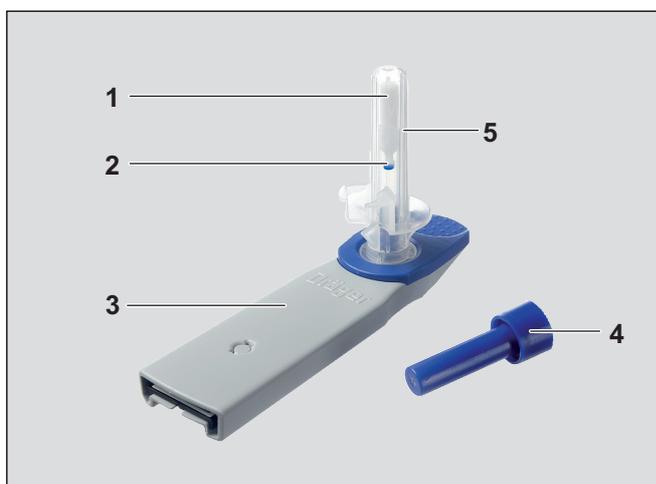
Additional information on using the equipment.

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## 2 Description

### 2.1 Product view

#### 2.1.1 Test kit



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- 1 Sampler
- 2 Sample amount indicator
- 3 Housing with test strips
- 4 Cartridge
- 5 Safety cap

#### 2.1.2 Analyzer



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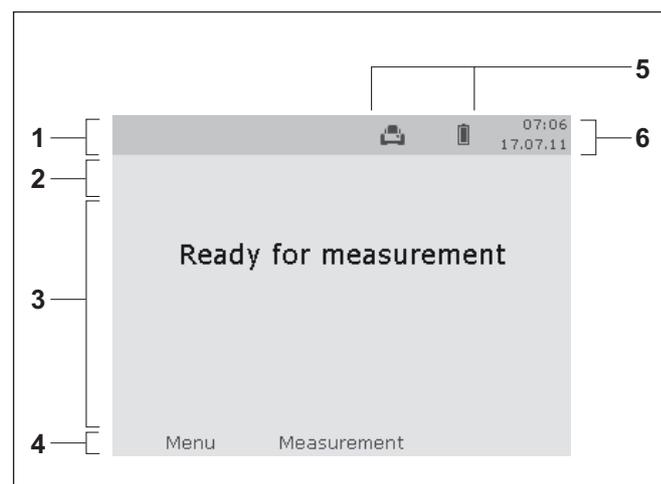
#### Front (door opened) and top sides

- 1 Operator control panel (one green OK-key, two blue softkeys)
- 2 Upper compartment (cartridge compartment)
- 3 Lower compartment (cassette compartment)
- 4 IRDA for printer communication and air outlet (lateral)
- 5 Carrying handle
- 6 Display
- 7 Air inlet

#### 2.1.3 Rear side (no illustration, connections are labelled)

- Socket for USB cable ("USB")
- Socket for keyboard and bar code scanner ("PS/2")
- Connection for power supply unit ("12V DC")

#### 2.1.4 Display



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- 1 Headline
- 2 Title bar
- 3 Variable section
- 4 Softkey identifier
- 5 Special symbols
- 6 Date and time

## 2.2 Functional description

The Dräger DrugTest 5000 test system consists of the unit-based development and evaluation of immunochemical test strips. Samples collected with the Dräger DrugTest 5000 test kit are processed by the Dräger DrugTest 5000 Analyzer. The Analyzer generates the required reaction temperature and brings the test strips, which are also part of the test kit, in contact with the sample. After the required reaction time controlled by the Analyzer the test strips are analysed by an optical method which measures the intensity of lines appearing on the test strip.

You will find details on the specific detection method used in special test kits in the respective Instructions for Use of the selected DrugTest 5000 test kit.

The rechargeable battery integrated in the Analyzer allows both stationary and portable use of the Dräger DrugTest 5000 test system.

## 2.3 Operating modes

The Dräger DrugTest 5000 Analyzer has three operating modes:

**Readiness:** The unit is ready to measure after switch on and successful self test. The three keys and the display of the unit light up.

**Standby:** After a predefined period of time of inactivity in readiness the unit will switch to standby. The keys on the unit are still lit, the display is switched off. You can quit standby mode and return the unit to immediate readiness by pressing any key.

**Automatic switch-off:** After a predefined period of time of inactivity in standby the unit will switch off automatically. It has to be switched on again before the next application.

## 2.4 State of charge of the integrated rechargeable battery



### CAUTION

The built-in rechargeable battery will be damaged if the unit is stored with a discharged battery.



### NOTICE

For optimal care of the battery, the unit should always be connected to the mains via the charger. The unit automatically ensures the best care of the battery (trickle charging).  
Recharge the battery immediately after each use and avoid storing the unit with incompletely charged battery.

The state of charge indicator in the title bar of the display shows a symbol for the current mode (mains-operated/portable operation) and the state of charge of the integrated rechargeable battery.

Illustrations of the various charge state symbols see "Explanation of Symbols" on page 34.

## 2.4.1 Mains operation

### Standard mode



The Analyzer is connected to an external power source.

### Restricted mode



The internal battery is not sufficiently charged or defective. A yellow warning triangle is depicted additionally. It is now possible to operate the unit while connected to the mains power; however, it is not possible to switch to portable operation.

## 2.4.2 Portable operation

During portable operation, a battery symbol indicates the charge status of the integrated rechargeable battery:

### Standard mode



The battery is fully charged.



With decreasing charge, the grey fill colour in the symbol will also decrease.



The battery is almost empty once only the outline of the icon is visible and a yellow warning triangle appears in addition.

### Almost discharged battery



The battery is running low, indicated by an unfilled red battery symbol. Immediately connect the unit to the external power supply to finish the measurement and avoid data loss.

### Completely discharged battery



The battery is fully discharged. This is indicated by an unfilled white battery symbol on a red background. Portable operation is not possible. Unless a power supply unit is connected, the unit will switch itself off a few seconds after this state is reached to avoid damaging the battery.

### Defective battery



Battery is faulty. A red "x" is displayed next to an unfilled battery symbol. Operating the Analyzer is only possible if a power supply unit is connected.

## 2.5 Intended use

The Dräger DrugTest 5000 test system consists of the Dräger DrugTest 5000 Analyzer and the Dräger DrugTest 5000 test kits. The test system is designed for the simultaneous, qualitative detection of substances or classes thereof in samples of human origin for diagnostic purposes (in-vitro diagnostic agent) and/or forensic use.

The detectable substances and the sampling medium to be used are defined by the DrugTest 5000 test kit used.

The Dräger DrugTest 5000 test system is a qualitative measuring system to detect searched substances or their metabolites which are contained in the sample in excess of certain concentration limits (cut-off) and therefore delivers only a preliminary analytical result (screening method). To obtain a confirmed analytical result a more specific method must be used. Gas chromatography/mass spectrometry (GC/MS) is the preferred method used in most cases.

A professional assessment of the result is required allowing for the further clinical consideration of the test subject. This applies especially if the preliminary result is positive.

You will find details on how to use the test kit in the Instructions for Use of the selected DrugTest 5000 test kit.

## 2.6 Approvals

The Dräger DrugTest 5000 test system is compliant with the European Directive for in-vitro diagnostics (98/79/EC).

If used as directed it is approved for use in medical environments throughout Europe. See chapters "Intended use" on page 33 and "Analysis method for confirmation" on page 53.

## 2.7 Explanation of Symbols

### 2.7.1 Special symbols



optional: external printer can be used



optional: Fast Mode



optional: external keyboard can be used



optional: Sensitivity Mode

### 2.7.2 Charge indicator, optical and acoustic signals (from firmware version 2.0.0<sup>1)</sup>)

When switched on, the charge status can be seen on the charge status symbol; when turned off, the Analyzer gives visual and audible feedback.

Display Charge status		Keyboard lights are flashing (Analyzer is switched off)	Tones (Analyzer is switched off)
	Mains connection established	no signal	one short tone: connected two short tones: disconnected
	Restricted mains operation	no signal	no signal
	Battery fully charged		Analyzer is connected to the mains
	Battery 2/3 charged		
	Battery 1/3 charged		
	Battery almost empty		
	Battery empty, emergency operation possible		
	Battery completely drained		
	Battery defective	no signal	

1) Contact your Dräger representative to perform a firmware update.

### 2.7.3 Explanation of used symbols

Symbols	Meaning
	Strictly follow the Instructions for Use
	Temperature limitation
	Manufacturer
	In vitro diagnostic medical product
	Separate collection of electric and electronic end-of-life units
	Contents sufficient for <n> tests

## 2.8 Scope of delivery

The following components are supplied with the Dräger DrugTest 5000 Analyzer:

Quantity	Name
1	Dräger DrugTest 5000 Analyzer
1	Battery charging power supply unit (12 V DC) with power cable
1	Vehicle supply cable (12 V)
1	Instructions for Use

The following components are supplied with the Dräger DrugTest 5000 Test Kit:

Quantity	Name
	Dräger DrugTest 5000 Test Kit, for the exact quantity see information on the packaging label: a. Test kit with sampler b. Safety cap with cartridge
1	Instructions for Use

### 2.8.1 Optional equipment

As system extensions Dräger offers additional accessories like, for example, printer, keyboard, bar code reader, carrier bag, training test kits and carrying case.

See "Order list" on page 50.

### 2.8.2 Ancillary Materials

- Dräger PSD 5000 (order no. 83 19 910)
- Disposable gloves (e.g. latex or nitrile gloves)

For technical assistance contact the local IVD dealer, Dräger or DrägerService.

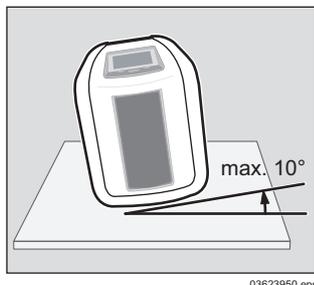
## 3 Use

### 3.1 Requirements for Use

The Dräger DrugTest 5000 Analyzer is delivered as a fully operational unit. Initial operation does not require any prior assembly or installation.

### 3.2 Preparations for Use

1. Position the Dräger DrugTest 5000 Analyzer on a flat, firm and horizontal surface. A maximum tilt angle of 10° around all axes of the Analyzer must not be exceeded.



2. Keep all air vents uncovered and clean.
3. Ensure specified ambient conditions:  
Ambient temperature between 5 °C and 40 °C  
Relative humidity between 5 % and 95 % RH



#### NOTICE

Condensation may occur if the Analyzer is moved from a cold environment to a warmer location.

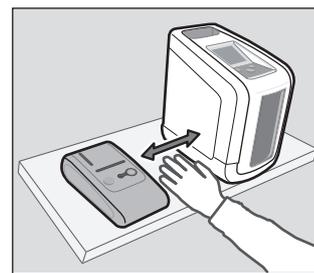
As a general rule, wait until the Analyzer has adopted the ambient temperature and is dry before it can be put into operation (at a change of ambient temperature from 0 °C to +20 °C about 1.5 hours).

Ensure that the packaged test cassettes and cartridges are at ambient temperature (if necessary, wait 15 min. for temperature to adjust).

4. Connect the external keyboard and align printer.
5. Connect battery charger 12 volt cable. If no external power supply is available, pay attention to the charge status of the analyzer.  
When switched off, the Analyzer will emit a beep the power pack is connected.
6. Recharge unit after use.

### 3.3 Align the printer

1. Position the Dräger Mobile Printer to the left of the Analyzer.
  - a. Dräger Mobile Printer and Analyzer stand on the same surface.
  - b. Front panel of the Mobile Printer and the Analyzer stand aligned next to each other.
  - c. The distance between the Dräger Mobile Printer and the Analyzer is about a hand's width.



The Dräger Mobile Printer automatically turns itself off after 4 minutes to save energy.

- Therefore only turn the Dräger Mobile Printer on just before printing or operate with the associated power pack, even when using non-rechargeable batteries.



#### NOTICE

Strictly follow the corresponding Instructions for Use.

### 3.4 Switch on Analyzer

1. Keep the **OK**-key pressed until the start window appears.
  - After successful completion of the automatic self-test the unit shows its readiness for operation with the message **Ready**.
  - Depending on the unit configuration different messages or input prompts can appear on the display after switch on.
2. Follow the instructions on the display.

### 3.5 Sampling



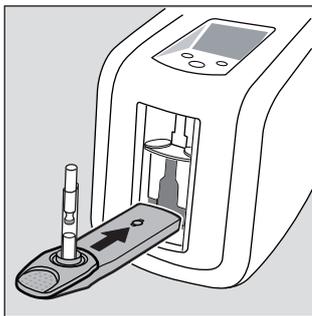
#### NOTICE

Check and follow the Instructions for Use of the relevant test kit!

Depending on the test kit used, follow the sampling procedure described in the accompanying Instructions for Use.

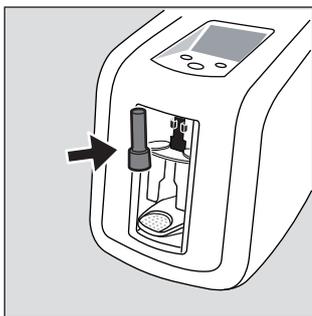
### 3.6 Analysing the sample

1. Make sure that the Analyzer is switched on and in **ready to measure** state.
2. Take the test cassette from the test person.
3. Open the Analyzer door and insert the test cassette into the lower compartment of the Analyzer, until it you hear it click into place.



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4. Insert the cartridge into the upper compartment of the Analyzer, until you hear it click into place.



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5. Close the door of the Analyzer. The Analyzer will start the evaluation automatically.  
Do not move the unit while performing the test!

A status bar on the display indicated the progress of the evaluation process.

#### Optional:

Depending on configuration, enter the following data, follow instructions on the display:

- Enter test person data.
- Enter user data.

Once the analysis is complete the Analyzer emits an acoustic signal.

To show results follow the instructions on the display.

6. Open the door of the Analyzer and remove the test cassette with the cartridge attached from the lower compartment of the Analyzer.



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7. Close the door of the analyzer.  
The analysis results are shown on the display.

#### Optional:

- Print test result.
- Save data record.

8. Confirm results by pressing the **OK**-key.

The Analyzer is ready for the next measurement.

### 3.7 Possible results of the analysis

Following the completion of the analysis the Analyzer shows the results of the analysis on the display. The results are displayed specifically for each tested substance.

27.10.11 03:50PM		10:08AM 01.11.11 088
Cocaine	Negative	
Opiates	Negative	
Benzodiazepines	Negative	
Cannabis-25	Negative	
Amphetamine	Negative	
Methamphetamine	Negative	
Metadone	Negative	
Confirm    Print		

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Four results of the analysis are possible:

#### Negative

The sample does not contain the wanted substance/group of substances or only in a concentration well below the limiting value of this detection reaction (see "Intended use" on page 33).

#### Positive

The sample does contain the wanted substance/group of substances or cross-reactive substances (e.g. metabolites of the wanted substance) in a concentration above the limiting value of this detection reaction (see "Intended use" on page 33).

#### Invalid

Each detection reaction has an integrated process control which is active during evaluation. Only if a detection reaction has been executed correctly will the Analyzer take this specific detection reaction into account. In case of errors in the reaction process the affected detection reaction will not be evaluated to exclude wrong results and is marked as "invalid". Only affected detection reactions are marked "invalid", not affected detection reactions are further evaluated and displayed as "positive/negative". Repeat the analysis if you require a result for the unevaluated substances/group of substances.

#### Not measured

Measurement was cancelled before the end of the analysis.

### 3.8 Switching Analyzer off

1. Keep **OK**-key pressed. The unit will switch off after approx. 3 seconds. The power supply cable should remain connected to charge the battery, until the unit is returned to the packaging, e.g. for transporting. When switched off, the Analyzer will emit two short beeps when the power pack is disconnected.
2. Follow the instructions on battery care on page 48.

In order to protect the optical components of the Analyzer against dust, the door of the Analyzer should remain closed (unless you are inserting or removing test kits).

## 3.9 Menu

The menu can be accessed by selecting the item **Menu** when the unit is ready to measure. Certain menu sections are only accessible after entering a four-digit password.

The menu is navigated with three unit keys by selecting the associated functions in the display (softkeys).

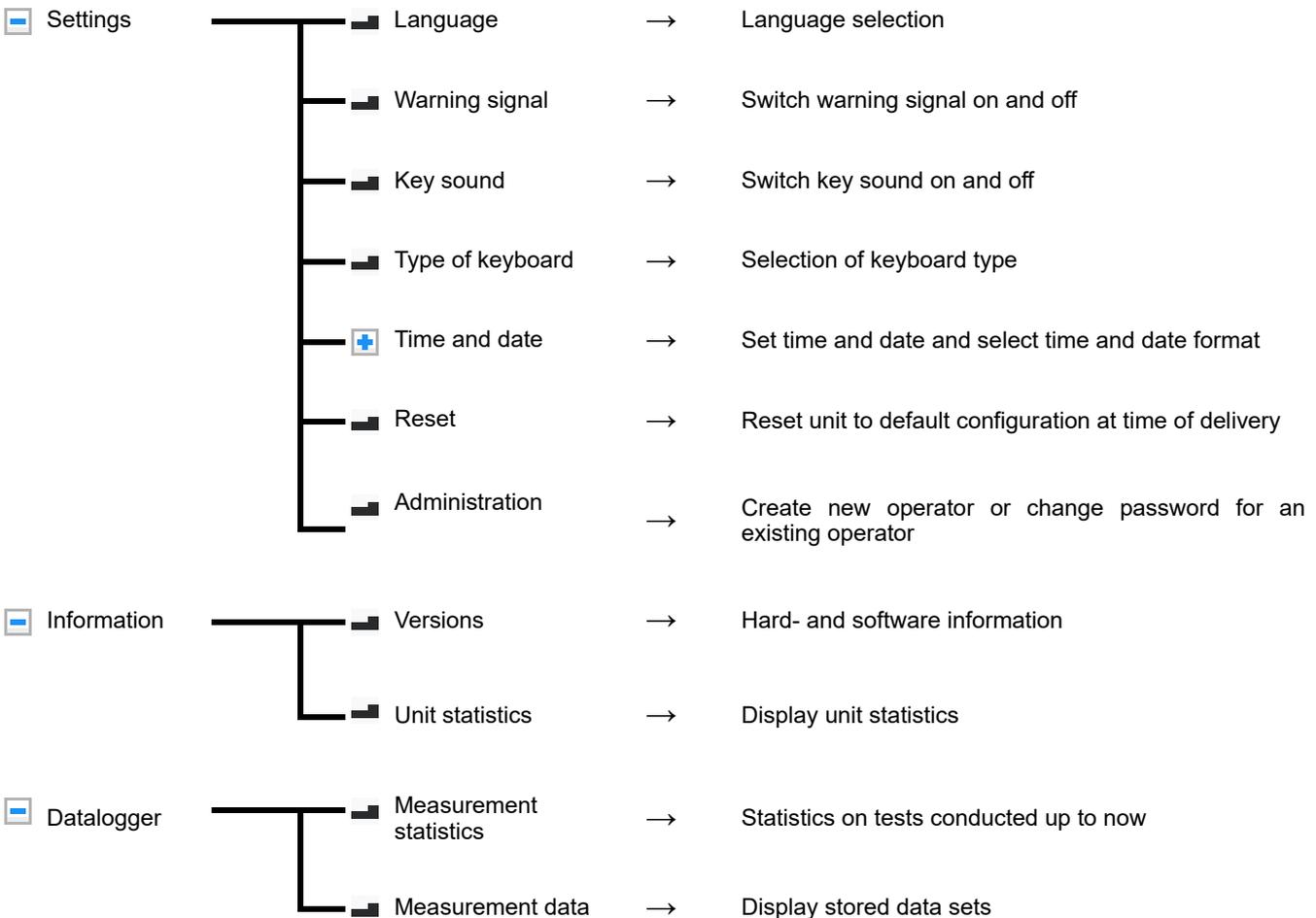
### 3.9.1 Navigation in the menu

Graphic symbols facilitate navigating the menu levels:

-  back up to superior menu level
-  Closed folder:  
This item contains further functions or sub-menus
-  Open folder:  
The functions and sub-menus shown here are contained in this item
-  Function:  
If selected, functions can be executed in a single step or several steps
-  Selection activated:  
Functions which can be selected and activated are enabled by pressing the -key.

### 3.9.2 Menu structure

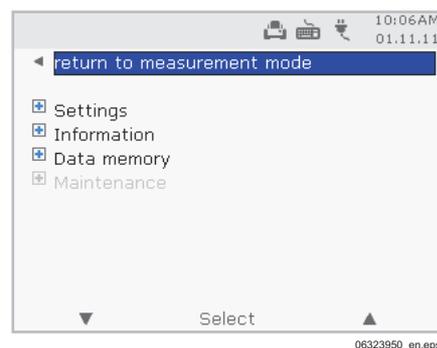
According to the current configuration of the unit menu functions can be either restricted or available only after entering a password.



### 3.9.3 Menu Settings

The Settings menu contains a number of functions for the configuration of unit parameters.

The menu functions can be activated if the unit is ready to measure by using the key **Menu**, selecting **Settings** and then selecting the particular function.



#### Language

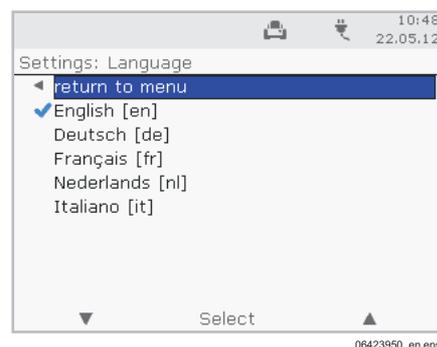
This function enables you to select the language of text in the display.

1. Use the keys ▼ and ▲ to select the desired language and the **OK**-key to activate it.

To terminate the function:

2. Select **return to menu** and press **OK**-key.

Texts will be displayed in the selected language only after you end this function.



#### Warning signal

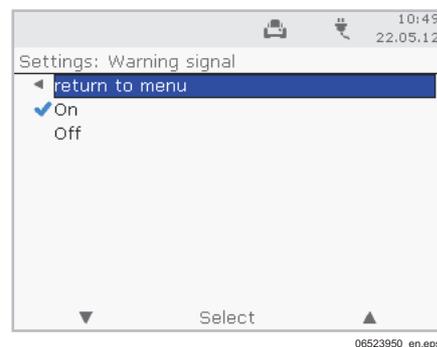
This feature allows you to activate/disable the alert.

1. Use the keys ▼ and ▲ to select the desired mode and the **OK**-key to activate it.

The alert is switched on or off.

To terminate the function:

2. Select **return to menu** and press **OK**-key.



#### Key sound

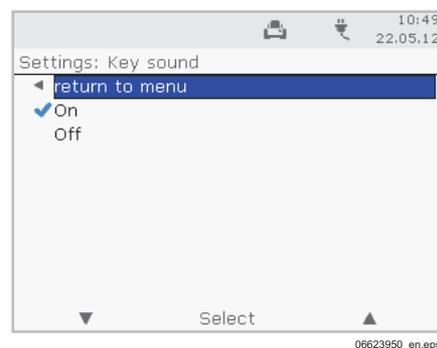
This feature allows you to activate/disable the key sound.

1. Use the keys ▼ and ▲ to select the desired mode and the **OK**-key to activate it.

The key signal is switched on or off.

To terminate the function:

2. Select **return to menu** and press **OK**-key.

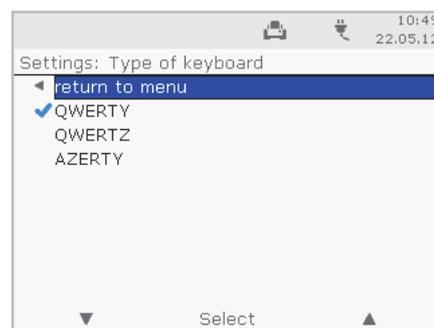


## Type of keyboard

This function allows you to select the used type of keyboard.

For example: QWERTZ German keyboard layout  
 QWERTY US keyboard layout  
 AZERTY French keyboard layout

1. Use the keys ▼ and ▲ to select the desired type and press the **OK**-key to activate.



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The selected keyboard type is activated.

To terminate the function:

2. Select **return to menu** and press **OK**-key.

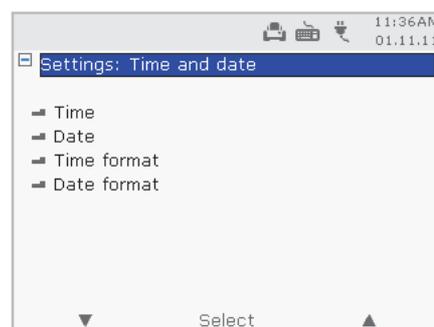
## Time and date

This submenu enables you to set the time and date and to select the time and date format.

### Set time

1. Select the **Time** function.
2. Use the keys ▼ or ▲ to set the first digit of the current time and confirm with **Select**.
3. Set the next digits in the same way and acknowledge.

Once the last digit is acknowledged, the **Time and date** submenu is displayed again.



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### Set date

1. Select the **Date** function.
2. Use the keys ▼ or ▲ to set the first digit of the current date and confirm with **Select**.
3. Set the next digits in the same way and acknowledge.

Once the last digit is acknowledged, the **Time and date** submenu is displayed again.

### Select time format

1. Select the **Time format** function.
2. Use the keys ▼ and ▲ to select the desired time format and the **OK**-key to activate it.

Possible selections: 12 hours AM/PM  
 24 hours

The submenu **Time and date** is displayed again.

## Select date format

1. Select the **Date format** function.
2. Use the keys ▼ and ▲ to select the desired date format and the **OK**-key to activate it.

Possible selections:

YYYY-MM-DD	year-month-day
DD.MM.YYYY	day-month-year
MM-DD-YYYY	month-day-year

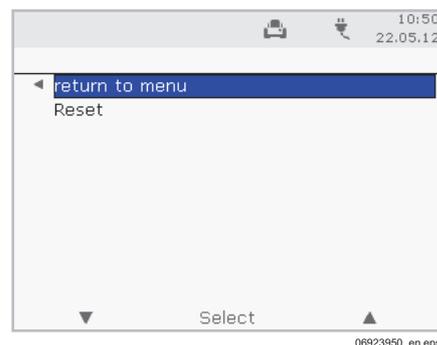
The submenu **Time and date** is displayed again.

## Reset

Use this function to restore the settings to the default configuration at time of delivery.

1. Use the key ▼ to select **Setting: Reset** and activate by pressing **OK**-key.

This function ends with the message **Settings restored**.



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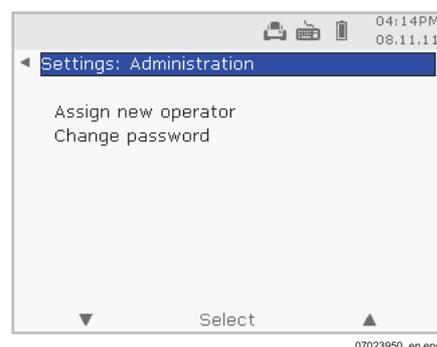
## Administration

### • Assign new operator

A new operator can be created using this function. A new user can only be created with an external keyboard.

1. Use the key ▼ to select **Create new operator** and the **OK**-key to activate.
2. Select Operator and press **OK**-key.
3. Enter user name with the keyboard and press **OK**-key.
4. Save the entered user name by pressing the **OK**-key.
5. Following this enter a password for the new user, press **OK**-key and enter the password again for confirmation.
6. Save the entered password for the new user with **OK**-key.

This function ends with the message **New operator assigned successfully**.



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## Change password

This function enables you to change a user password.

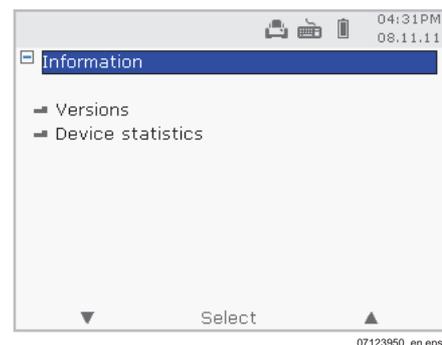
1. Use the key ▼ to select **Change password** and press the **OK**-key to activate.
2. Select **Password** and press **OK**-key.
3. Enter previous user password and press **OK**-key.
4. Enter new user password and press **OK**-key.
5. Following this enter the new user password again for confirmation.
6. Save the new user password with **OK**-key.

This function ends with the message **Password changed successfully**.

### 3.9.4 Menu Information

The menu contains two functions for interrogating the unit parameters.

The menu functions can be activated if the unit is ready to measure by using the key **Menu** , selecting **Information** and then selecting the particular function.



#### Versions

This function is used to display unit parameter versions.

1. Use the key ▼ to select **Versions** and press the -key to activate.
2. End the function by pressing the -key.

#### Device statistics

This function is used to display detailed statistics about the unit.

- Last service 1
  - Last service 2
  - Counter service 1
  - Counter service 2
  - Measurements
  - Connection time [min]
1. Use the key ▼ to select **Unit statistics** and press the -key to activate.
  2. End the function by pressing the -key.

### 3.9.5 Menu Data memory

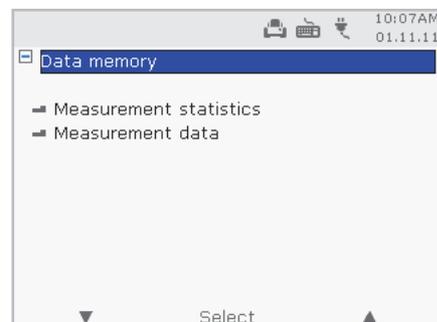
The menu contains two functions that allow information about data memory to be queried.

The menu functions can be activated if the unit is ready to measure by using the key **Menu**, selecting **Data memory** and then selecting the particular function.

#### Measurement statistics

This function is used to display the total number of measurements in datalogger overall and the number of positive measurements in datalogger.

1. Use the key ▼ to select **Measurement statistics** and press the **OK**-key to activate.
2. End the function by pressing the **OK**-key.



#### Measurement data

This function is used to display a list of measurements in data memory with date, time and result.

1. Use the key ▼ to select **Measurement data** and press the **OK**-key to activate.
2. In the list of measurements you can select the desired measurement with ▼ or ▲ and confirm with the **OK**-key to call up a detailed view of the selected measurement.
3. The detailed view can be printed out; end the function with the **OK**-key.
4. Select **return to menu** and press **OK**-key.

### 3.9.6 Service Menu

Service functions are only accessible for DrägerService.

## 3.10 Configuration

The unit can be connected to a PC by using the integrated USB interface. With the aid of Dräger Diagnostics<sup>1)</sup> Software qualified users and DrägerService can perform updates of the unit configuration.

Should an update of the unit configuration be necessary, DrägerService will provide configuration packages. Updates of the unit configuration can be required to change or extend the Analyzer operational sequences or to expand the range of applicable test kit types.

### 3.10.1 Load configuration package

A configuration package consists of a file ending in ".ddt". Copy the file to a directory on the computer's hard drive. Only then continue.

### 3.10.2 Connect unit

1. Make sure that the Analyzer is switched on and in **ready to measure** state.
2. Connect the Analyzer to a PC on which the Dräger Diagnostics software is installed. Use a suitable USB cable (e.g. AG 02 661) for this purpose.

### 3.10.3 Change configuration

1. Launch Dräger Diagnostics Software.
2. Select the "DrugTest 5000" module in the top left.
3. Then on the left choose **Select Analyzer**. Select the serial number of the unit that is to be updated.
4. Now select **Update Analyzer**.
5. Then select the desired update package (\*.ddt) in the dialogue box on the right hand side.
6. By clicking on **Upload** the configuration is loaded into the Analyzer. A progress bar shows how far the update has advanced.



#### CAUTION

Do not disconnect the Analyzer from the PC, turn off the Analyzer or press any button on the Analyzer until the update is complete!

Some update packages may require the Analyzer to be restarted. This restart is performed automatically.

---

Once the update is complete, a message appears from Dräger Diagnostics.

7. The Analyzer can now be disconnected from the PC.

### 3.10.4 Data memory readout and other functions

The Dräger Diagnostics software provides many other functions. Please contact DrägerService for a detailed software manual.

---

1) Available free-of-charge at [www.draeger.com](http://www.draeger.com)

## 4 Troubleshooting

The following table describes possible faults and system messages.

If problems occur during use of the unit that are not listed in the following table or that cannot be resolved by following the listed corrective measures, contact DrägerService or a Dräger authorized service organisation (see section "Troubleshooting and repair" in chapter "Maintenance" on page 48).

Faults	Cause	Remedy
No screen display within 10 seconds after switching on the unit	Battery discharged and no external power supply connected	Connect battery charging power supply unit and establish mains power supply.
Acoustic warning signal and display of the message <b>Close door</b>	The door of the Analyzer was opened during analysis	Close Analyzer door.
Acoustic warning signal and display of the message <b>Remove test cassette</b>	During the automatic self test a test cassette was found in the unit	Open Analyzer door, remove test cassette and close door again.
Smoke development / pungent smell	Wrong battery charging power supply unit used	Use supplied battery charging power supply unit. Should the problem persist: Contact Dräger.

### 4.1 Warnings and error messages on the display

Warnings and error messages are displayed in plain text. Follow any instructions associated with warnings and error messages.

### 4.2 Problems during saliva sampling

The sample adequacy indicator on the sampler changes to blue during the oral fluid absorption thereby indicating that sampling can be stopped. To make sure that the user can check the sample adequacy indicator, the test subject has to interrupt the oral fluid sampling at certain intervals (approx. 1 minute) and remove the sampler for a short time from the mouth for appraisal.

Any kind of blue colouration of the sample adequacy indicator shows that the saliva sampling can be stopped. This also applies to cases where only sections of the indicator are blue or where the blue colouration is unevenly distributed.

If the collection of the oral fluid sample was carried out properly, the test will typically take 30 seconds to 2 minutes. A critical prerequisite is that the sampler is inserted deep enough into the mouth and moved about the oral cavity to make sure it wipes over the oral tissue and underneath the tongue.

Contingent upon low salivation ("dry mouth") the oral fluid sample collection can take longer in exceptional cases. If this occurs, you can stop the sampling after four minutes and perform the analysis with reduced oral fluid sample volume.

If a minimal volume of oral fluid has been collected and the oral fluid sample contains high drug concentrations, the chance for a positive test result is very good.

## 5 Maintenance

The Dräger DrugTest 5000 Analyzer is a sturdy device requiring a minimum of maintenance and care.

### 5.1 Maintenance intervals

We recommend that the unit be serviced on a regular basis every 12 months.

Servicing only by DrägerService or a Dräger authorized service organisation.

We recommend signing a service contract with Dräger.

### 5.2 Cleaning

If necessary, wipe the outer surfaces of the unit with a damp, soft cloth that has been dipped in a mild soap solution or a commercial laboratory detergent (e.g. isopropanol).



#### CAUTION

Do not immerse the unit in liquids and make sure no liquids enter into the connectors!

The inside of the unit must not be cleaned by users.

### 5.3 Maintenance work

#### 5.3.1 Troubleshooting and repair

If problems should arise during the use of the unit, which cannot be solved by referring to the table "Troubleshooting" on page 47, you should notify DrägerService or a Dräger authorised service organisation.

Some faults may require that the unit is returned for repair to Dräger.

For this case we have a repair substitution concept: Directly after the receipt of the repair request a replacement unit is sent to you.

1. The faulty unit is packed into the packing of the replacement unit and the enclosed address label affixed.
2. Send the faulty unit to Dräger as soon as possible.

#### 5.3.2 Battery maintenance



#### CAUTION

The built-in rechargeable battery will be damaged if the unit is stored with a discharged battery.

For optimal care of the battery, the unit should always be connected to the mains via the charger. The unit automatically ensures the best care of the battery (trickle charging). Recharge the battery immediately after use and avoid storing the unit with incompletely charged battery.

The Analyzer is equipped with an integrated lead storage battery. It consumes a small standby current even if switched off, which can discharge a fully charged battery in approx. **two months**. The battery capacity can be retained at an optimum and for the long term if periods of low charge are avoided.

To do so the following measures are required:

- Always operate the Analyzer with the power pack if it is not being used in mobile applications. A permanent connection to the mains does not damage the integrated battery, but in fact preserves its capacity.
- For applications in vehicles use the 12V cable.
- In mobile mode, if the unit indicates a low battery charge, connect the battery charger and fully charge the battery as soon as possible.
- During storage always leave the battery charger connected.
- For long term storage of the unit where it is not possible to connect the battery charger, fully charge the Analyzer before placing it into storage and fully charge the battery every **six weeks**.

## 6 Disposal of electrical and electronic equipment



EU-wide regulations for the disposal of electric and electronic appliances which have been defined in the EU Directive 2002/96/EC and in national laws are effective since August 2005 and apply to this device. Common household appliances can be disposed of using special collecting and recycling facilities. However, as this device has not been registered for household usage, it must not be disposed of through these means. The device can be returned to your national Dräger Sales Organisation for disposal. Please do not hesitate to contact the above if you have any further questions on this issue.

## 7 Technical data

Supply voltage	12 V DC (11 to 15 V DC)
Power input	typically 3 A
Dimensions ( W x H x D)	200 mm x 250 mm x 220 mm
Weight	4.5 kg (including battery)
Temperature range	Operation: +5 °C to 40 °C (+41 °F to 104 °F) Storage/ Transport: -20 °C to 60 °C (-4 °F to 140 °F)
Humidity range	5 to 95 % r. h., non-condensing
Interfaces	optical IRDA (printer), PS/2 (for external keyboard or scanner), USB slave (for communication with PC)
Time of Measurement	depending on test kit, 4:15 to 8:30 minutes
Storage capacity	500 data sets with test results

## 8 Order list

Name and description	Order code
<b>Dräger DrugTest 5000 Analyzer</b> including battery charging power supply unit, mains cable and instructions for use	83 19 900
Keyboard compact (PS/2, dimensions approx. 28.2 x 13.2 x 2.4 cm):	
"QWERTZ" – key assignment German	83 15 095
"QWERTY" – key assignment English	83 15 497
"AZERTY" – key assignment French	83 15 142
Dräger Mobile Printer	83 19 310
Paper for Dräger Mobile Printer (5 rolls)	83 19 002
Carrier bag Dräger DrugTest 5000 Analyzer	83 22 675
Transport case	83 19 925
Battery charger 12 V with mains cable for EU, UK, USA, AUS	83 15 675
Vehicle power cable 12 V	
Power cable from car cigarette lighter sockets to Dräger DrugTest 5000 Analyzer	83 12 166
USB connection cable for communication with a PC	AG 02 661
Barcode scanner	AG 02 491
Dräger DrugTest 5000 test kit Package containing 20 pieces	83 19 830
Dräger DrugTest 5000 training test kit Package containing 20 pieces	83 19 970
Dräger DCD 5000	
Sample transportation and storage container with integrated sampler.	83 19 910
Dräger SSK 5000	
Collection and analysis of surface samples	83 20 490
Dräger Diagnostics	www.draeger.com
Software for Analyzer configuration	
Dräger DrugTest 5000 Test System - Technical Handbook	www.draeger.com

## 9 Appendix

### 9.1 Dräger DrugTest 5000 test kit

#### 9.1.1 General remarks

The Dräger DrugTest 5000 test system uses test kits to collect and analyse samples. Depending on the configuration of the test kits, you can detect various substances or categories (groups) of substances.

The DrugTest 5000 Analyzer recognises which test kit you are using on the basis of information deposited in each test kit. This information is used to make use of each test kit according to its requirements and to evaluate the results of the analysis.

Beyond that, each test kit carries batch-specific calibration data for the Analyzer and transfers them to the Analyzer prior to evaluation. This ensures that all evaluations are performed batch-independent without further action by the user and with uniform quality.

This chapter contains universally applicable information on the various test kits. You can find details on a specific test kit in the respective Instructions for Use enclosed in the test kit pack.

#### 9.1.2 Notices and precautions



##### NOTICE

The test kit can only be processed with the Dräger DrugTest 5000 Analyzer!

The packing material of the test cassette must be completely sealed. Do not use the test cassette if the seals are not intact.

In order to prevent the contamination of the sampler with foreign bodies, open the package just prior to use.

Do not touch the sampler before and after sampling with bare hands and observe usual hygiene precautions.

#### 9.1.3 Compatibility of the Analyzer with new test kit configurations

Different test kit configurations ("panel types") are available for the Dräger DrugTest 5000 test system. A database integrated into the Analyzer contains information on the available panel types at the time of delivery.

When the range of panel types is enlarged, the Analyzer needs to be updated before the new panel types can be used. See "Configuration" on page 46.

#### 9.1.4 Test principle

The Dräger DrugTest 5000 test system is based on the immunoassay principle of competitive inhibition. Drugs present in the sample compete with drugs on the test membrane for the cohesion of microparticles coated with antibodies.

##### Samples:

The various test kits have been evaluated for the respectively indicated samples. The sample need not be specially treated. The sample is absorbed directly into the porous sampler integrated into the test cassette. The analysis is started after sampling by placing both the test cassette and the cartridge into the Analyzer. The Analyzer transfers the sample to the test cassette and the test development is initiated automatically.

##### Test:

The sample interacts with the microparticles coated with antibodies and with drug conjugates on the test membrane. If the sample is devoid of drugs, the antibodies can react freely with the drug conjugates and a signal is created on the test membrane. If drugs are contained in the sample they link to the microparticles coated with antibodies and as a consequence the created signal is weaker. The Analyzer detects the signal created by a specific sample and decides if the signal comes from a preliminarily positive ("not negative") sample.

##### Quality control:

Each test membrane has another integrated sample-independent antibody/antigen reaction. After the sample has been processed successfully, antibodies on the reagent membrane bind the antigens on the microparticles thus creating a control signal. This signal is also detected by the Analyzer and used to decide if a test is valid or not.

##### Data management:

Test results are stored in the Analyzer memory. All data can be printed out. Additional details on the data management options of the Analyzer can be found in chapter "Menu Data memory" on page 45.

#### 9.1.5 Storage and stability

Test cassettes and cartridges must be stored in the original foil pouch at a temperature between 4 and 30 °C (39 to 86 °F). Do not use test cassettes if the foil pouch is damaged.

The test cassette must be used immediately after you open the foil pouch.

Do not use the test kit if the stamped use-by date has been exceeded.

#### 9.1.6 Scope of delivery

- Dräger DrugTest 5000 Test Kit, for the exact quantity see information on the packaging label:
  - a. Test kit with sampler
  - b. Safety cap with cartridge
- 1 Instructions for Use

### 9.1.7 Quality control

A quality check at regular intervals belongs to good analytical practice and is also possibly required by local authorities.

Internal control: An integrated process control is performed during every analysis. A control signal is generated when a test was properly developed. If this control signal fails to appear, the Analyzer will not evaluate the corresponding analysis.

External control: Based on the test properties a quality control can be conducted on site by using a drug-free sample and processing it. The result for all analyses for this sample must be NEGATIVE. Information on commercial positive controls for this test are available from DrägerService.

### 9.1.8 Confirmation of results

The Dräger DrugTest 5000 test system is a qualitative measuring system to detect searched substances or their metabolites which are contained in the sample in excess of certain concentration limits (cut-off) and therefore delivers only a preliminary analytical result (screening method). To obtain a confirmed analytical result a second sample must be taken and analysed by another more specific method in an authorised laboratory. Gas chromatography/mass spectrometry (GC/MS) is the preferred method used in most cases. When using saliva samples, the second sampling should be done with the Dräger DCD 5000 (order no. 83 19 910). See "Analysis method for confirmation" on page 53.

### 9.1.9 Limitations

- The Dräger DrugTest 5000 test kit was designed for the analysis of samples collected with the test kit's sampler. The use of liquids other than those specified in the Instructions for Use of the respective test kit or samples absorbed by another method can lead to incorrect results.
- A positive result during the test will only show that the substance concentration lies above the limiting value of the test kit. A negative result can indicate that the sample is either free of drugs or their concentration lies below the limit.
- The reagents used in the test kits are especially meant for the detection of the specified substances. Nevertheless, structurally similar prescribed and over-the-counter drugs can react with the reagents and cause false positive results.
- Due to the properties of immunoassays cross-reactive substances or unspecified interactions can interfere with the test and produce false results. Technical errors and procedural errors can also contribute to incorrect results.
- Rare false results may occur as a result of non-specific interactions (physiological variation, state of health, contamination of the sample with food or other substances, etc.) (see also "interfering substances"). Technical errors and procedural errors can also contribute to false results.
- The taking of samples should be closely monitored. If there is a suspicion that the sample collection was tampered with, repeat the test with a new test kit.

### 9.1.10 Interfering substances

Rare false results may occur as a result of non-specific interactions (physiological variation, state of health, contamination of the sample with food or other substances, etc.) (see also "interfering substances").

Each test kit panel type was tested for the interaction with various interfering substances. Detailed information on possible interactions of interfering substances with a specific test kit can be found in the Instructions for Use of the respective test kit.

### 9.1.11 Specificity

The reagents used in the test kits are especially meant for the detection of the specified substances/substance groups. Nevertheless, prescribed and over-the-counter drugs with structurally similar active agents can cross-react with the reagents and cause false positive results.

In order to provide support for users during the evaluation of positive results of the analysis, test kits were subjected to broad investigation of their specificity and cross-reactivity. In the Instructions for Use of the test kits you will find tables and charts with the substances examined per detection reaction and the concentrations where a positive analysis result of this detection reaction is possible if they are exceeded. Furthermore, it should be borne in mind that the presence of several similar substances whose individual concentrations are below the limit can together produce a positive result.

### 9.1.12 Accuracy

In order to verify the clinical performance of the test kits on site results were compared with the results of the appropriate secondary samples. The results of these comparative measurements can be found in tabular form in the Instructions for Use of the test kits.

## 9.2 Analysis method for confirmation

The Dräger DrugTest 5000 principle is based on the so-called antigen-antibody reaction. Here the antibody specifically binds with its "paratop" the corresponding "epitop" of the antigen. This bond which is facilitated by hydrogen bridge bonds, ionic bonds, hydrophobic interactions and van der Waals forces is a balance reaction which is accordingly subject to the law of mass action. With a sufficiently optimised test system it is possible – in dependence on the antigen – to prove them in the femtomol range and even quantify them <sup>1)</sup>.

### 9.2.1 Why confirm?

State-of-the-art immunological testing procedures – especially screening test kits – are designed to make sure that from a defined substance concentration a positive result with a probability of >90 to 95 % is actually positive <sup>2)</sup>.

The remaining "vagueness" of this analytical statement and the fact that immunochemical screening results are also affected by cross-reactivity and interferences of other – possibly chemically very similar – substances must always be considered. Positive results must be confirmed by a second, independent procedure such as, for example, gas chromatography (GC) or liquid chromatography (LC) with subsequent mass spectrometry (MS). Within the scope of mass screenings and screening programmes it is recommended to conduct a defined random sample (e.g. 10 to 20 %) of the negative results on site with the help of GCMS or LCMS.

### 9.2.2 Chromatography

The term chromatography comprises physical methods whereby substances are separated by distribution between a static (stationary) and a moving (mobile) phase.

### 9.2.3 Gas chromatography

GC is a very efficient separation method whereby a dissolved mixture of substances (the sample) is guided with the aid of a stream of gas (mobile phase) over a stationary phase. In doing so the sample is split into its individual components. The inert carrier gas is normally helium.

The stationary phase consists of a 10 to 50 m long quartz column with an internal diameter of 0.2 mm which is charged on the inside with an especially thin film of a separating material. The individual components of the sample leave the separating column after a specific period of time (retention time) and can then be analysed by a sensitive detector.

In the field of drug analysis a mass spectrometer has been successfully connected in series for many years for this purpose (GC/MS) <sup>3)</sup>.

### 9.2.4 Mass spectrometer

Mass spectrometers consist of an ion source in which gaseous molecules are ionised, a mass analyser separating ions

according to their mass/valency ratio ( $m/z$ ) and a detector counting the number of generated ions. As result of the analysis a characteristic mass spectrum is generated for each substance which shows which ions have been formed in which relative quantities. This allows a definite analyte identification.

## 9.3 Collecting another saliva sample for confirmation

### 9.3.1 Precautions & Warnings

Samples containing material collected from human beings should be treated as potentially infectious; safe laboratory methods must be applied <sup>4)</sup>.

### 9.3.2 Preanalytics

Preanalytics is as crucial and decisive for the quality of the lab results as instrumental laboratory analytics themselves.

The Dräger DCD 5000 (order no. 83 19 910) is designed for the collection of approx. 0.4 millilitres of oral fluid and the provision of the collected oral fluid sample in a transportation tubule for lab analysis. Details on the performance capacity of the Dräger DCD 5000 are included in the accompanying Instructions for Use.

If required two Dräger DCD 5000 can be plugged together to conduct a simultaneous dual sampling. Following this the samplers are disconnected, enclosed in transportation tubules and analysed separately.

### 9.3.3 Sampling – Dräger DCD 5000

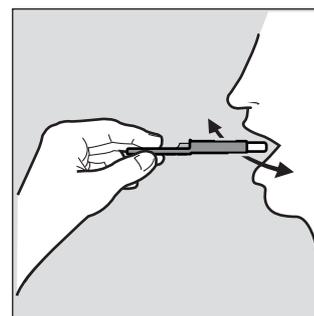


#### NOTICE

Strictly follow the corresponding Instructions for Use.

1. Remove sealing plugs from the transport tube.
2. The test subject takes an oral fluid sample collector – keep the sealing plugs in a safe place.

3. The test subject takes the sampler into the cheek pouch and gently moves it from one side of the mouth to the other.  
The test subject should not chew or suck on the sampler.  
Observe the process!

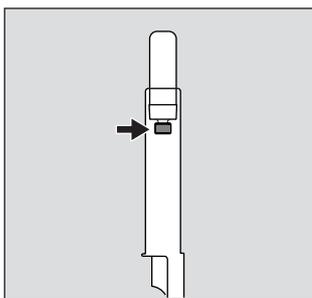


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1) Polzius, R. and Manns, A., (2002) Dräger booklet 373, p. 23-28  
 2) Luttmann, W. et al. (2006) The experimenter, immunology, Elsevier GmbH Munich  
 3) Schwedt, G. (1992): Pocket atlas of analytics, published by Georg Thiem, Stuttgart

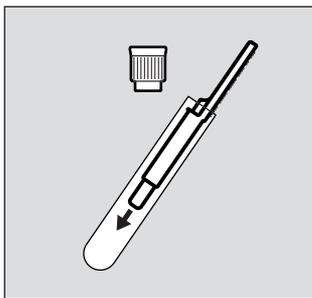
4) cf. e.g. Biosafety in Microbiological and Biomedical Laboratories (HHS Publication No.[CDC] 93-8395).

- Once the sample amount indicator changes colour to blue, an adequate sample amount has been collected and the test subject can remove the sampler from the mouth.



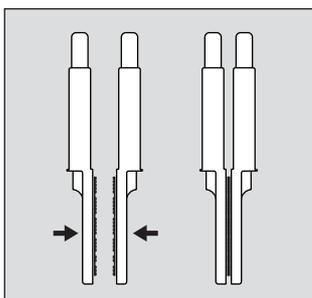
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- Take the oral fluid sampler from the test subject and insert the oral fluid sample collector with the sampler first into the open transportation tube.
- Close the transportation tube with the sealing plugs and clearly label the sample on the tube.



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- In case of increased sample demand conduct sampling with other samplers or by simultaneous dual sampling.



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### 9.3.5 Shipping supplies

Dräger DCD 5000 sampler including transportation tubule, required address labels, order forms and suitable shipping packaging can be obtained from your Dräger Safety representative or the representative of the laboratory of your choice. Always ship in accordance with applicable local, state, or federal regulations.

- If required stick a safety seal/originality label over the sealing plug.
- Complete the order form for the laboratory.
- Pack the transportation tube for shipping, or alternatively for storage. Shipping or storage has to be in accordance with local or federal regulations (e.g. by using special envelopes).
- Send samples to the analysis service of the Dräger Safety AG & Co. KGaA, Revalstr. 1, D-235650 Lübeck.



#### NOTICE

Potential mailing errors:

Error variations by mailing of up to 30 % are known for diverse clinical parameters and chemical provisions<sup>1)</sup>. In the meantime some laboratories offer their own pickup or courier services.

- Vorlaender, K. O. (1980): Diagnostics using immunological methods, published by Georg Thiem, Stuttgart

### 9.3.4 Sample labelling

In order to ensure the identity of a sample it needs to be labelled carefully. Ensure that these details correspond to the details on the order form.





Directive 98/79/EC



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