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Gebrauchsanweisung

en  20

Instructions for Use

Dräger Alcotest® 6820 med



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1 For your safety

1.1 General safety notes

- Before using this product, carefully read the Instructions for Use.
- Strictly follow the Instructions for Use. The user must fully understand and strictly observe the instructions. Use the product only for the purposes specified in the Intended use section of this document.
- Do not dispose of the Instructions for Use. Ensure that they are retained and appropriately used by the product user.
- Only trained and competent users are permitted to use this product.
- Comply with all local and national rules and regulations associated with this product.
- Only trained and competent personnel are permitted to inspect, repair and service the product. Dräger recommends a Dräger service contract for all maintenance activities and that all repairs are carried out by Dräger.
- Use only genuine Dräger spare parts and accessories, or the proper functioning of the product may be impaired.
- Do not use a faulty or incomplete product and do not modify the product.
- Notify Dräger in the event of any component fault or failure.
- This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.
- Electrical connections to devices which are not listed in these Instructions for Use should only be made following consultation with the respective manufacturers or an expert.

1.2 Definitions of alert icons

The following alert icons are used in this document to provide and highlight areas of the associated text that require a greater awareness by the user. A definition of the meaning of each icon is as follows:



CAUTION

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

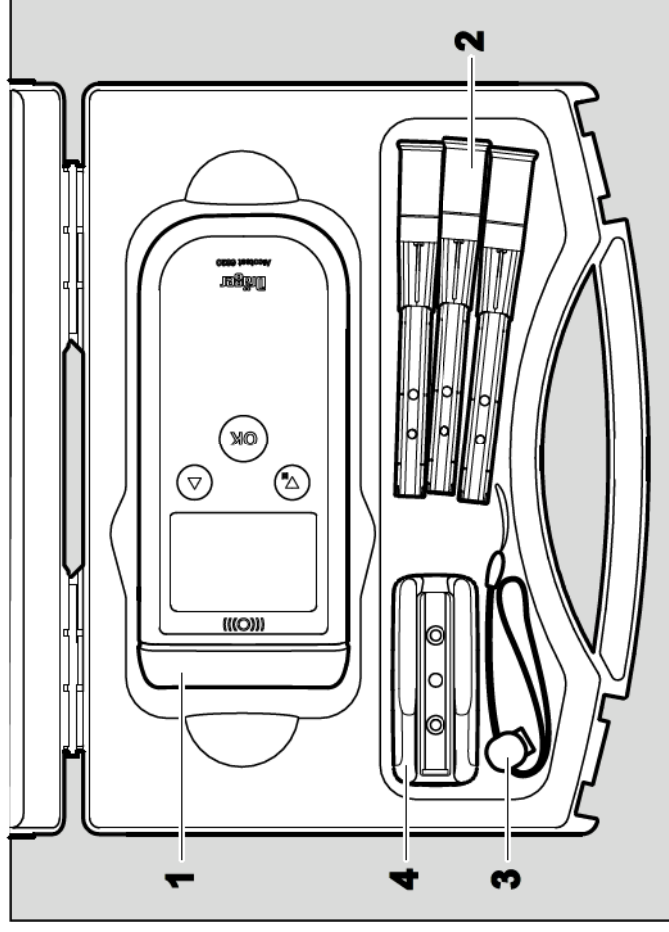


NOTICE

Indicates additional information on how to use the product.

2 Description

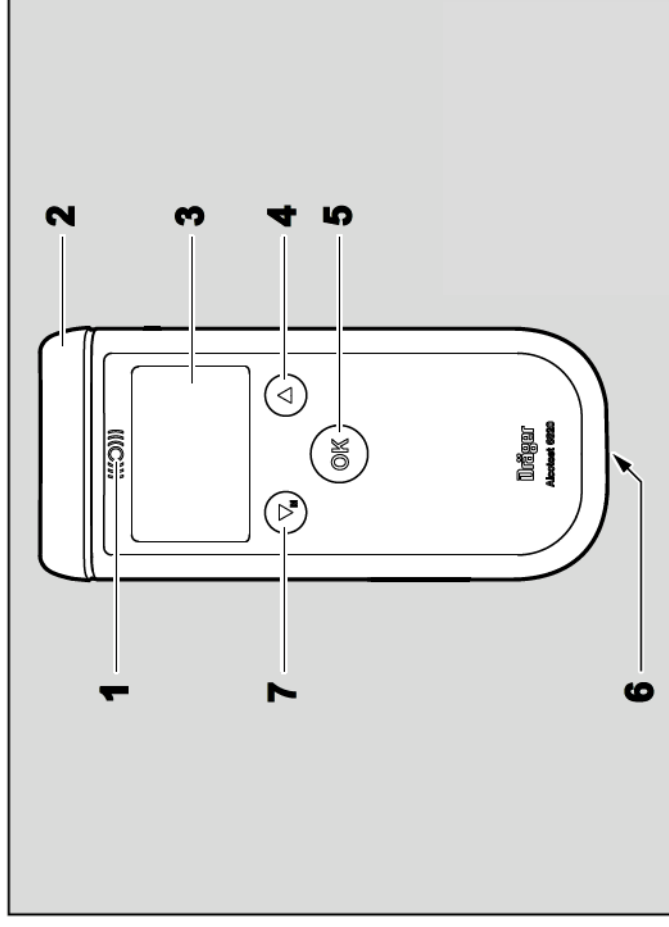
2.1 Product overview



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Case

- 1 Dräger Alcotest 6820 med measuring device (incl. 2 batteries)
- 2 Mouthpieces, 3 pieces (not for reuse) (2)
- 3 Wrist strap
- 4 Mouthpiece receptacle



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Measuring device

- 1 Light red/green/yellow - optical interface
- 2 Mouthpiece receptacle
- 3 Display
- 4 Up key
- 5 OK key
- 6 Charging / communications socket
- 7 Down/Menu key

2.2 Intended use

For rapid measurement of breath alcohol concentration – for example for diagnosis of vascular injuries in the urology during transurethral resections of the prostate, TUR-P, or in the gynaecology during transcervical resections of the endometrium, TCRE, after previous application of an ethanol containing rinsing solution, at the emergency reception area for testing patients for previous alcohol consumption, or for the detection of alcohol consumption before methadone substitution.



CAUTION

Do not use mobile phones within a distance of 10 metres from the instrument. Mobile phones and portable or mobile HF communication equipment can cause interference to electrical and electronic medical appliances, thereby putting patients at risk.¹⁾

Do not use the instrument together with flammable gases or flammable anaesthetic agents. Fire hazard!

- 1) Dräger medical devices comply with the interference immunity requirements of the specific standards for the products. However, depending on the design of the mobile phone and situation of use, field strengths may occur in the immediate environment of a mobile phone that exceed the values of the standards quoted and therefore may cause interference.

2.3 Device symbols and displays

The measured breath alcohol value is specified in the basic device setting, in the unit of mg/L (= milligrams of ethanol per litre of breath). The device can be converted to all common units of measurement.

2.3.1 Device symbols



Symbol for "See Instructions for Use".

2.3.2 Keys

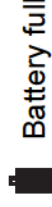


OK key
Confirms entries or selected functions.
Key for switching the device on and off.

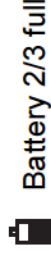


DOWN/Menu and UP key
Setting values and selection of menu functions.

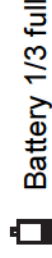
2.3.3 Battery symbols - Indicates the batteries' state of charge:



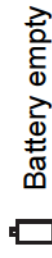
Battery full



Battery 2/3 full

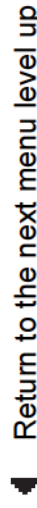


Battery 1/3 full



Battery empty

2.3.4 Menu



Return to the next menu level up



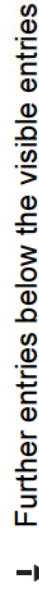
Menu item with submenu



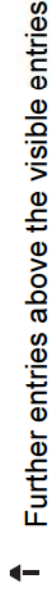
Open menu item



Available function

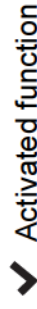


Further entries below the visible entries

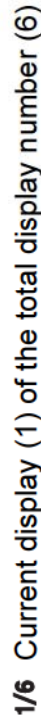


Further entries above the visible entries

2.3.5 Function



Activated function



Current display (1) of the total display number (6)

3 Use

3.1 Prerequisites

- The ambient air must be free from alcohol and solvent vapours (disinfectants).
- Maintain an adequate distance from mobile telephone antennas and transmitter sites so as not to impair the function of the device.
- Observe a waiting period of at least 15 minutes after the last oral alcohol intake!
Residual alcohol in the mouth can distort the measurement. Even aromatic beverages (e. g. fruit juice), alcoholic mouth sprays, medical juices and drops and, belching and vomiting may result in false data. Also observe a waiting period of at least 15 minutes in these cases. Rinsing the mouth with water or non-alcoholic drinks does not replace the waiting time!
- The test person should breathe regularly and calmly before the sample is taken. Avoid breathing in and out quickly through the mouth.
- The device records breath samples with a volume greater than 0.3 L. The test subject must be able to deliver this volume as a minimum. If the volume of the breath sample is over 0.3 L and less than 1.2 L, the message "Low volume" is shown on the display as well as the measurement result.
The displayed alcohol content of the breath sample does not reflect the blood alcohol concentration until the volume exceeds 1.2 L breath volume. All alcohol tests of breath samples with the message "Low volume" may display a lower result than the actual blood alcohol concentration.
- Always have a functional secondary device or alternative measures available for emergency applications or other critical measurements.

3.2 Preparations for use

3.2.1 Inserting or replacing the batteries / rechargeable batteries



CAUTION

Explosion hazard!

Do not throw used batteries/rechargeable batteries into a fire or open them by force. Do not recharge alkaline batteries. Batteries/rechargeable batteries must be disposed of in accordance with local and national regulations.



NOTICE

To ensure that the device can be used again immediately after the alkaline batteries or the rechargeable NiMH batteries are discharged, it is recommended to have replacement batteries available.

Replace the batteries within 5 minutes, otherwise the save time will be reset and must be set again.

1. Undo the screw plug on the battery lid (e. g. using a coin) and remove the battery lid.
2. Insert the batteries or rechargeable batteries and make sure that the polarity is correct.
3. Close the battery lid and tighten the screw plug.

Required batteries/rechargeable batteries:

- 2 x 1.5 V alkaline type (AAA, LR6, AA) or,
- 2 rechargeable batteries - 1.2 V NiMH (AAA, LR6, AA)

3.2.2 Charging rechargeable NiMH batteries (optional)



CAUTION

Damage to the device!

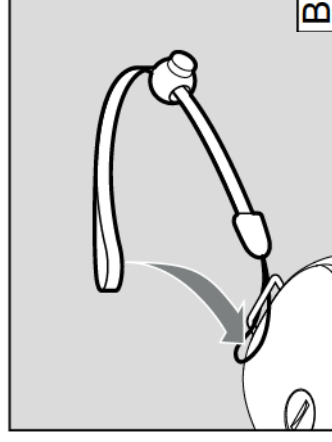
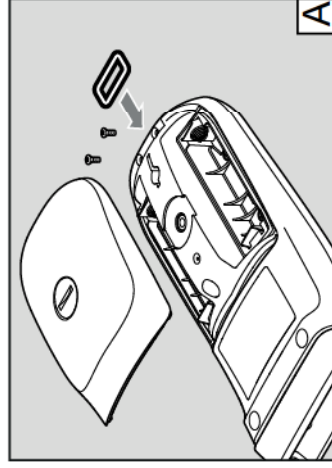
Only use the charger specified in the order list and only charge NiMH rechargeable batteries, as the device may be damaged otherwise.

NiMH rechargeable batteries can be recharged directly in the device.

- Connect the charger (Order No. 83 16 991) to the charging / communications socket.
During the charging process, the battery display pulses from empty to full.

3.2.3 Fitting the wrist strap

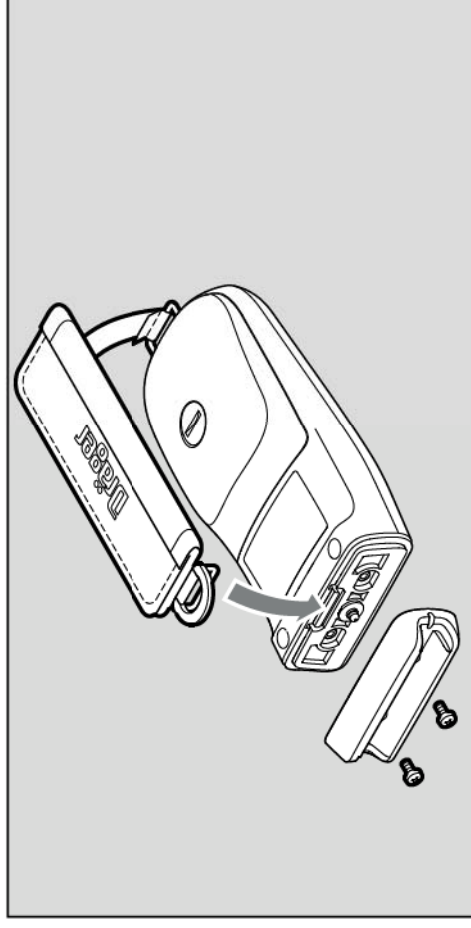
1. Undo the screw plug on the battery lid (e.g. using a coin) and remove the battery lid.
2. Insert the eye supplied in the opening and fix with the screws (2x) supplied.
3. Guide the fastening lug of wrist strap through the eye.
4. Pull the lower part of the wrist strap through the strap.
5. Close the battery lid and tighten the screw plug.
6. Pull the cord adjuster over the wrist strap.



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3.2.4 Fitting the wrist strap (optional)

1. Undo the screws (2x) of the mouthpiece receptacle and remove the mouthpiece receptacle.
2. Undo the screw plug on the battery lid (e.g. using a coin) and remove the battery lid.
3. Insert the upper eye of the wrist strap in the upper opening on the device.
4. Place the mouthpiece receptacle on the device and fix with the screws (2x).
5. Insert the bottom lug of the wrist strap in the bottom opening on the device and fix with the screws (2x) of the wrist strap.
6. Close the battery lid and tighten the screw plug.



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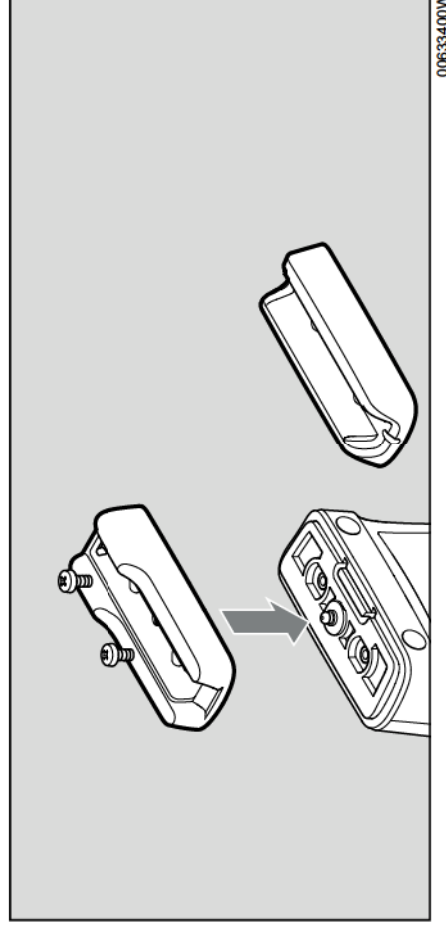
3.2.5 Replacing the mouthpiece receptacle

NOTICE

Replacing the mouthpiece receptacle is not permitted in all countries. Please observe national regulations!

The device is supplied with 2 different mouthpiece receptacles.

1. Undo the screws (2x) on the mouthpiece receptacle.
2. Remove the mouthpiece receptacle.
3. Insert new mouthpiece receptacle on the device, observe the desired mouthpiece orientation.
4. Fix the mouthpiece receptacle with screws (2x).

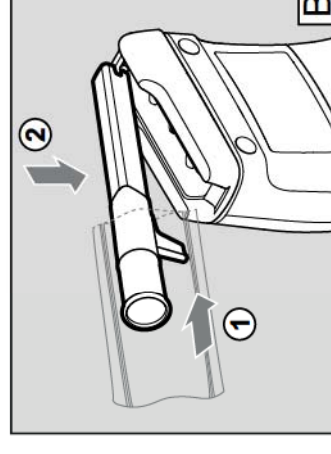
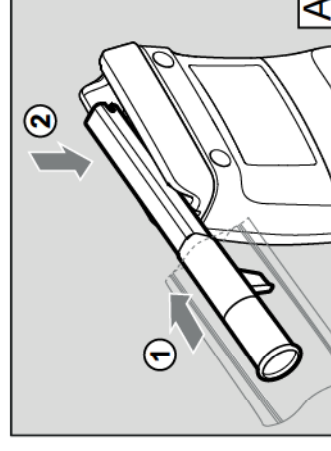


3.2.6 Attaching the mouthpiece

NOTICE

Use a new mouthpiece for each measurement. ②

1. Remove the mouthpiece from the packaging. For reasons of hygiene, leave the protective wrapping around the mouth contact area until the mouthpiece is firmly attached to the device.
 - With mouthpiece receptacle A:
 - With the fluted markings (press-on surface) facing upwards, attach the mouthpiece at an angle, push it upwards and press it into the mouthpiece receptacle. The mouthpiece audibly snaps into place. The mouthpiece can be used facing to the right or to the left.
 - With mouthpiece receptacle B:
 - Attach the mouthpiece at an angle to the mouthpiece receptacle and press it into the receptacle. The fluted markings (press-on surface) on the mouthpiece face upwards while this is done. The mouthpiece audibly snaps into place.



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2. Remove all packaging.

3.2.7 Switching the device on and off

To switch the device on:

- Press and hold the  key for approx. 1 second until the start window appears. A self check is carried out. Device information is displayed (e.g. date for the next service).



If the next service date has expired:

- have the device calibrated, e.g. by Dräger Service.

To switch the device off:

- Keep the  key pressed. The device will switch off after approx. 2 seconds.



NOTICE



The device will switch off automatically approx. 4 minutes after the last use.

When the batteries or rechargeable batteries are discharged, the battery symbol flashes and then the device switches off automatically.

3.3 Automatic measurements



CAUTION

- Do not allow any high breath alcohol concentrations on the sensor, e.g., by rinsing the mouth with a high proof alcohol shortly before the measurement, as this will shorten the service life of the sensor. Observe a waiting period of at least 15 minutes after the last oral intake of alcohol!

- Keep at a distance of at least 10 meters from the antennas of mobile phones and transmitting stations



NOTICE

A new mouthpiece must be inserted for each test subject.

With automatic measurement, the device takes the sample automatically as soon as the test subject has given a breath sample that is sufficient into the mouthpiece of the device and the end of the breath sample has been recognised by the device.

To carry out an automatic measurement:

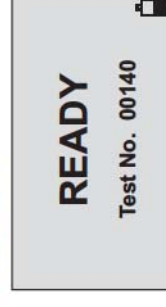
1. Insert new mouthpiece into the mouthpiece receptacle (see section 3.2.6 on page 26).
2. Switch on the device (see section 3.2.7 on page 27).

After approx. 2 seconds, **READY** will appear on the display and a short acoustic signal will sound. At the same time the current test number is displayed.

The light flashes green.

The device is ready to use.

3. Ask the test subject to blow into the mouthpiece evenly and without interruption, as long as possible.

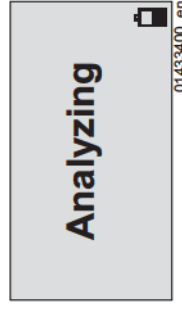
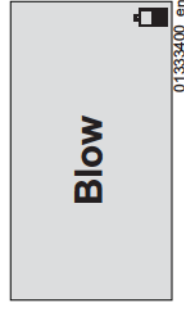


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While the breath sample is given, a continuous tone sounds, the green light is illuminated and, **Blow** appears on the display.

When the breath sample has been given, the green light goes out, the continuous tone will stop and a short clicking sound can be heard.

On the display, **Analyzing** appears.



The test result will appear on the display after 5 to 25 seconds (depending on the device temperature and the measured concentration).

The measurement result is displayed with the corresponding unit. The units are factory-set to mg/L (milligrams of ethanol per litre of breath) and can be changed via the menu. In

addition to the result of the measurement, an acoustic signal is output, e.g.:

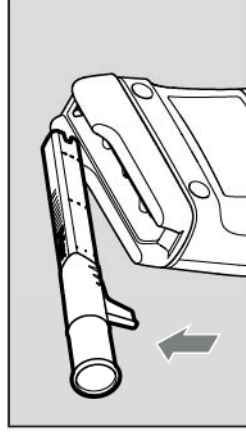
- PASS (low range) – 1 x,
- ALERT (middle range) – 2 x,
- FAIL (high range) – 3 x,

NOTICE

While the result is shown on the display, a measurement record can be generated with the optional Dräger Mobile Printer (Order No. 83 19 310). Completed tests can be re-printed from the **Last Tests** menu.



4. Push the mouthpiece upwards out of the mouthpiece receptacle.
5. Dispose of the mouthpiece in accordance with local regulations.



3.3.1 Carrying out another measurement

- Press the  key to prepare for a new measurement.

While the device is waiting until it is ready to take a measurement, see section 11 on page 34, a seconds counter and a rotating bar appear on the display.



NOTICE

Switching off the device intermittently will not reduce the waiting period until it is ready to take a measurement!



3.3.2 Errors when giving the breath sample

If the volume of the breath sample is too small, **Insufficient volume** will appear on the display.

A short signal tone sounds and the light flashes red.

- Press the  key to repeat the measurement.

After approx. 2 seconds, the device is ready for measuring.



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In the case of very irregular exhalation, e. g. sudden termination or suction at the end of the breath sample, **Blow interruption** appears on the display.

A short signal tone sounds and the light flashes red.

- Press the  key to repeat the measurement. After approx. 4 to 30 seconds, the device is ready for measuring.



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3.4 Additional sampling options

Further information, e.g. on configuration, can be found in the Technical Manual.

3.4.1 Passive sampling

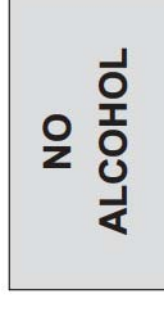
With passive sampling, the sampling is initiated manually by the device user. Possible applications include the testing of ambient air or the breath of uncooperative (e. g. unconscious) persons for the presence of alcohol.

To carry out passive sampling:

1. Switch on the device (see section 3.2.7 on page 27).

2. Hold the device which is ready for measuring into the air to be analysed, **without a mouthpiece**.

3. Briefly press the  key.
Display for "No alcohol present":



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Display for "Alcohol present":

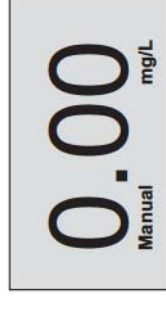
4. Press the  key for a new measurement.

3.4.2 Manual sampling

Sampling can also be triggered manually if the test subject cannot produce the required minimum breath volume.

1. Preparation as for automatic measurement (see section 3.3 on page 27).
2. When **Blow** appears on the display after exhalation has begun, briefly press the  key.

When the result is displayed, the message **Manual** also appears on the display.



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4 Menu

Further information, e.g. on selecting other units of measurement, can be found in the Technical Manual.

4.1 Calling up the menu

1. Switch on the device (see section 3.2.7 on page 27).
When **READY** appears or when the rotating bar is displayed, the menu functions can be accessed.
2. Briefly press the  key.
The menu will be displayed.

4.2 Operation

- Select the functions using the  and  keys.
- The selected function is displayed inverted.
- Activate the selected function with the  key.
- Selecting  **Back to measurement** brings the device back into the measurement mode when the  key is pressed.



NOTICE

If no key is pressed within 120 seconds, the device automatically returns to the measurement mode.

4.3 Menu items

■ Last tests

The device displays the last 5,000 tests.
A smaller number can be set in the range 0 - 249.

Select the tests with the  and  keys. Go back with the  key.

The data sets can be transferred to a PC using the "Diagnostics" PC software.

■ Last cal. date

Displays the date of the last calibration and the last accuracy test.
Go back with the  key.

■ Date & time

Displays the current date and the time. Go back with the  key.

■ Date (optional)

Displays and sets the date and the date format. Change with the  and  keys; confirm with the  key.

■ Time (optional)

Displays and sets the time, the time format and the automatic changeover from summer to winter time. Change with the  and  keys. Confirm with the  key.

■ Select language (optional)

Selects the display language. Change with the  and  keys. Confirm with the  key.

■ Set contrast

Change with the  and  keys. Confirm with the  key.

■ Check accuracy (optional)

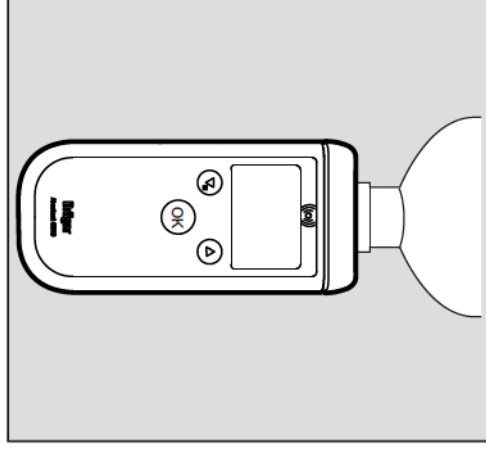
Additional test of the measuring accuracy within the calibration period.



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5 Functional test/Quality assurance

- Perform a daily functional test.
- Quality assurance must be performed in accordance with §4a MPBetreibV (German act on the installation, operation and use of medical devices) and "RiliBÄK zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen" (Guideline of the German Medical Association on quality assurance for medical laboratory examinations), part B1, 2.1.1.
- Place the device ready for measurement without mouthpiece onto the opening of a bottle containing a solution with a concentration of approx. 1 g ethanol per 1 litre water see section 12 on page 36 or approx. 1% ethanol rinsing solution.
Alternatively drop some drops of the solution on an absorbent paper and place the instrument without mouthpiece above the paper.
- Press  button shortly.
The instrument performs a measurement and displays the result. As soon as the sensitivity of the instrument for alcohol has been verified the display shows **"ALCOHOL"**, the red light is lit.
- Press  button shortly; the instrument is ready for use.
- If the display shows **"NO ALCOHOL"** and the green light is lit:
Repeat functional test.
- If **"NO ALCOHOL"** shows again: Calibrate the instrument; by trained service personnel for example by Dräger Service.



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6 Device faults

An error message (see section 7 on page 32) will appear if a device fault occurs.



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The number that appears below the message is used for service functions. If the fault persists even after the device has been switched on and off several times and/or the battery has been removed (for a minimum of 2 seconds) and re-inserted, contact Dräger Service.

7 Troubleshooting

Fault	Cause	Remedy
Device switches off automatically.	Device has been ready to measure for longer than 4 minutes. (Rechargeable) batteries drained.	Switch the device back on. Replace see section 3.2.1 on page 24 or charge batteries.
Menu is exited automatically in measuring mode.	Device automatically jumps to the measuring mode after 120 seconds.	Select menu item again.
Device cannot be switched on.	Batteries discharged.	Insert new batteries or charge batteries.
Volume too low / sample invalid.	Test subject is blowing intermittently or not hard enough.	Have test subject blow with more force and without interruption.
Service date expired.	The service interval has expired.	Perform a safety check. e.g. by Dräger Service.
No text on the display.	Device fault, potentially caused by electrostatic discharge.	Remove the batteries/rechargeable batteries (minimum of 2 seconds) and re-insert, contact Dräger Service, if required.
Error message on the display	Cause	Remedy
Calibration Test incorrect	Calibration test not successful.	Repeat calibration test; contact Dräger Service if necessary.
↑↑↑	Measured value exceeds the display range (residual alcohol possibly present in the mouth).	Observe a waiting period of at least 15 minutes after the last oral alcohol intake.
Internal System ERROR with error number	Device fault, measurement not possible.	Remove the batteries/rechargeable batteries (minimum of 2 seconds) and re-insert, contact Dräger Service, if required.
Service Date expired	The service interval has expired.	Perform a safety check. e.g. by Dräger Service.
Incorrect rechargeable batteries	No rechargeable NiMH batteries in the device.	Remove incorrect batteries/rechargeable batteries. Insert rechargeable NiMH batteries and charge.

8 Maintenance

8.1 Maintenance intervals

As necessary:

- Replacing the batteries, see section 3.2.1 on page 24.

Every six months:

- Check calibration¹⁾.

8.1.1 Functional test/Quality assurance:

Recommended daily. (Page 31)

8.1.2 Measurement performance test:

- Every six months, including calibration by trained service personnel, e.g. by Dräger, including test of calibration (in Germany according to § 6 MPBtreibV).

8.2 Cleaning



CAUTION

Damage to the device! Do not immerse the device in liquids and make sure liquids do not penetrate the connectors.

- Do not submerge in liquid – liquid must not enter the sockets.
- Do not sterilize in hot steam.
- Do not sterilize with ethylene oxide.

To clean:

- Wipe with a disposable cloth.

1) Further information on calibration can be found in the Technical Manual.

To disinfect:

- Wipe with a disposable cloth soaked in isopropyl alcohol.
- Wait at least 15 minutes until next measurement.

9 Storage

Do not store the device in environments which contain alcohol. The device consumes power, also when switched off. Therefore, remove the battery for extended disuse.

CAUTION



Damage to the device!

For long term storage (longer than 6 months), remove the batteries or rechargeable batteries from the device. This will prevent damage due to leaking battery acid.

10 Disposal

Dispose of the product in accordance with the applicable rules and regulations.



This product must not be disposed of as municipal waste. This is indicated by the adjacent icon.

You can return this product to Dräger free of charge. For information please contact the national sales organisations and Dräger.



Batteries and rechargeable batteries must not be disposed of as municipal waste. This is indicated by the adjacent icon. Collect and dispose of batteries and rechargeable batteries at battery collection centres, in accordance with applicable regulations.

11 Technical data

Measurement principle

Electrochemical sensor

Measuring range

Breath alcohol concentration 0,00 to 2.50 mg/L

(Ethanol mass per breath volume at 34 °C and 1013 hPa.)

Blood alcohol concentration

0,00 to 5.00‰

(Ethanol mass per blood volume and/or mass at 20 °C and 1013 hPa.

For the above data, a conversion factor of 2100 is used for breath and blood alcohol concentration data (works setting, country-specific conversion factors can be configured).

Indication range

The measurement result will be shown on the display if it is within the measuring range.

If the measurement result is out of range, the display will show three arrows "↑ ↑ ↑" indicating that the measuring range has been exceeded.

Ambient conditions

During operation

–5 to +50 °C
10 to 100 % R.H.
(non-condensing)
600 to 1400 hPa

During storage

–40 to +70 °C

Sample conditions at the end of the breath sample

automatic measurement

Breath volume

>0.3 L (pre-set)

Breath flow

>3 L/min (pre-set)

Measurement accuracy

Standard deviation of the repeatability with ethyl alcohol standard

up to 0.50 mg/L

0.008 mg/L

≥ 0.50 mg/L

1.7 % of the measured value

up to 1.00 ‰

0.017 ‰ or

≥ 1.00 ‰

1.7 % of the measured value
whichever value is higher

Sensitivity drift

typically 0.4 % of the measured value/month

Cross sensitivity to anesthetic gases

none

Waiting time until device is ready to use	
1. Measurement	approx. 2 s
after a previous measurement of: (breath alcohol concentration specified)	
0.25 mg/L	20 s
0.50 mg/L	40 s
1.00 mg/L	80 s
> 1.5 mg/L	120 s
after a previous measurement of: (blood alcohol concentration specified)	
0.50 ‰	20 s
1.00 ‰	40 s
2.00 ‰	80 s
> 3.00 ‰	120 s
Values for other units of measurement can be calculated accordingly (see section 11 on page 34).	
Calibration	
every 6 months	
Safety inspection	
every 6 months	
Functional test/ Quality assurance	
Recommended daily. Quality assurance must be performed in accordance with §4a MPBetreibV (German act on the installation, operation and use of medical devices) and "RiliBÄK zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen" (Guideline of the German Medical Association on quality assurance for medical laboratory examinations), part B1, 2.1.1.	

Size	
Dimensions	65 mm x 147 mm x 39 mm (W x H x D)
Weight	approx. 260 g
Power supply	
Batteries	2 pcs. 1.5 V Alkaline (LR6, AA) approx. 1.500 measurements
Rechargeable batteries	2 pcs. 1.2 V NiMH (LR6, AA)
Interface	
USB	for data transfer to PC
Classification per EC Directive 93/42/EEC	
Measuring instrument	Class I with a measuring function
Mouthpieces	Class I
Protection class	
IP 54	
UMDNS-Code	
17-475	
DIMDI registration number	
DE/CA01/102/040	
CE mark	
Electromagnetic Compatibility Directive (2014/30/EC)	
The device meets the requirements of EN15964 . It can be configured according to the standard.	

12 Order list

Name and description	Order no.
Dräger Alcotest 6820 med (Measuring device, 3 mouthpieces, batteries, hand strap and case)	83 26 270
Accessories	
Dräger Mobile Printer	83 19 310
Case for Dräger Alcotest 6820	83 17 920
Leather case for Dräger Alcotest 6XXX (black) (belt attachment)	83 17 911
Leather case for Dräger Alcotest 6XXX (yellow) (Device can be operated from the case), with compartment for 4 mouthpieces, no belt attachment	83 17 931
Diagnostics PC program for data communication with Dräger Alcotest 6820	83 17 915
PC communication cable	83 19 715
Printer communications cable with Mini USB (for Dräger Mobile printer)	83 18 657
Charger (power source) for charging the rechargeable NiMH batteries in the Dräger Alcotest 6810	83 16 991
Technical Manual	90 23 833

Name and description	Order no.
Spare parts	
Mouthpieces with non return valve (100 pieces)	37 05 618
Alkaline battery (1 piece)	13 35 804
NiMH battery (1 piece)	83 17 912
Paper (5 rolls), shelf life 7 years (for Dräger Mobile printer)	83 19 002

Accessories for functional test:

Ethanol standard solution 1.21 g/L (1 x 500 mL) 67 28 838



Richtlinie 93/42/EEC über Medizinprodukte
Directive 93/42/EEC concerning Medical Devices

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Dräger Safety AG & Co. KGaA

Revalstraße 1

23560 Lübeck, Germany

Tel +49 451 882-0

Fax +49 451 882-20 80

www.draeger.com