

# AlcoTrue<sup>®</sup> E

Breathalyser for personal use



Operating instructions

## **Liability**

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bluepoint MEDICAL GmbH & Co. KG guarantees that the product delivered has been thoroughly tested to ensure that it meets its published specifications.

AlcoTrue® is a registered trademark of bluepoint MEDICAL GmbH & Co. KG

## **Warranty**

bluepoint MEDICAL GmbH & Co. KG warrants the products manufactured or distributed by them to be free from faulty materials and workmanship for a period of 15 months from date of original shipment to first end user except for wear parts, disposable products or products which have a stated guarantee longer or shorter than 15 months. bluepoint MEDICAL GmbH & Co. KG will perform warranty service at its factory.

The obligations for bluepoint MEDICAL GmbH & Co. KG under this guarantee shall be limited to repair, or at bluepoint MEDICAL GmbH & Co. KG 's option, replacement of necessary parts or assemblies and shall not include shipping costs or other incidental damages.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the products must specify both the name of the product and its serial number as written on the label on the product.

Use of the equipment for other than its intended use, or if it has been repaired by anyone except bluepoint MEDICAL GmbH & Co. KG or a bluepoint MEDICAL GmbH & Co. KG authorized service centre, or altered or modified or used without following the instructions in the user manual, will void this guarantee.

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## 1. Safety considerations

### ***Strictly follow the instructions for use***

Handling the device requires full understanding and strict observation of these operating instructions.

The device is intended only for the application described herein.

### ***Maintenance***

Calibration and maintenance work must be carried out by authorised service personnel only. Only original parts from bluepoint MEDICAL GmbH & Co. KG may be used for repairs.

Only the accessories specified in the order list shall be used.

### ***Safety symbols***



Important information on a topic or procedure, or conditions that may lead to damage or malfunction of the device



Indicates potential harmful conditions that may lead to injury

### ***Disposal***



Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)

## 2. Intended use

### Intended use

AlcoTrue®E is a mobile breathalyser for personal use with 3x AA alkaline battery. AlcoTrue®E is intended for quick and accurate determination of alcohol concentration in a person's breath.

**NOTE:** AlcoTrue®E is not an evidential measuring instrument and cannot be used bindingly to determine if a person after use of alcohol can drive a vehicle or can operate a machine. Measurements with AlcoTrue®E or similar kind of "pre-test breathalysers" are not a evidential proof of for example prior a court suitable. With AlcoTrue®E usage it can only serve to confirm an initial suspicion.

### Calibration

AlcoTrue®E is provided with a standard calibration by bluepoint MEDICAL GmbH & Co. KG

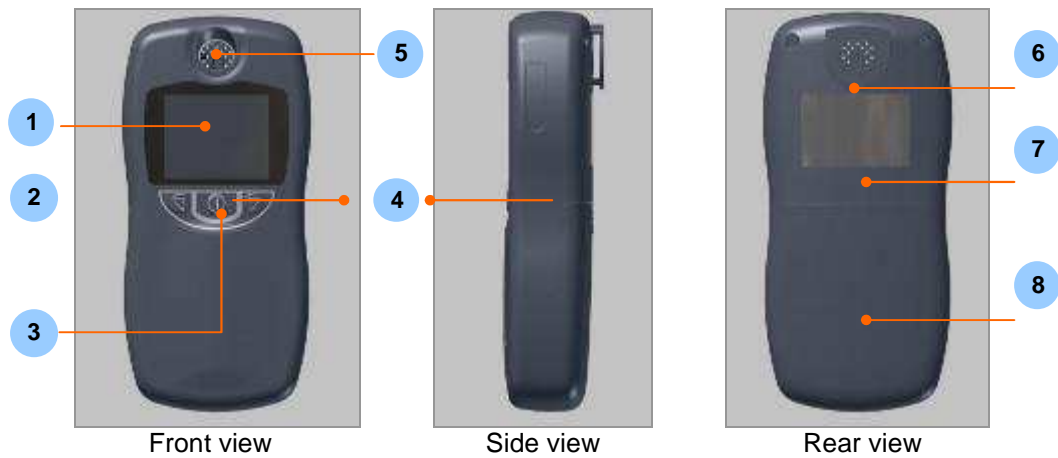
The periods of calibration validity are 1000 measurements or 12 months, after calibration period expires the device will require re-calibration. Using of AlcoTrue®E with an expired device calibration has a risk of obtaining erroneous results.




The device can either be re-calibrated by bluepoint MEDICAL GmbH & Co. KG or an authorised service partner.

The calibration overdue is displayed after device "Self test" procedure with **<CAL>**





### 3. Device

#### 3.1 AlcoTrue® E – device components




No.	Description	No.	Description
1	Display	5	Device inlet
2	Menu 	6	Device outlet
3	“ON/OFF/Confirm” button 	7	Device label
4	Background light 	8	Battery compartment lid

#### 3.2 Device label-symbols

	Consult user manual for detailed operating instructions!	<b>S/N</b>	Serial number
	CE certified to 89/336/EWG	<b>P/N</b>	Product number
	Manufacturer		Observe disposal regulations!

## 4. Battery information

### 4.1 Insert/exchange batteries

Insert batteries before use or exchange batteries if the battery symbol on the display indicates .

- Press onto the lock of the battery compartment and remove cover



- Insert batteries in battery case. Observe correct polarity and correct position when inserting the batteries!
- Close battery cover.



**Use only 3 x 1.5V Type Alkaline (Mignon, LR6, AA). Never mix batteries of different brands and different discharge levels. Always replace all batteries at once. Remove the batteries if the device is to be stored or not used for a long period of time.**

### 4.2 Battery level indications



Battery full



75% battery capacity



50% battery capacity



25% battery low 25%




Battery empty

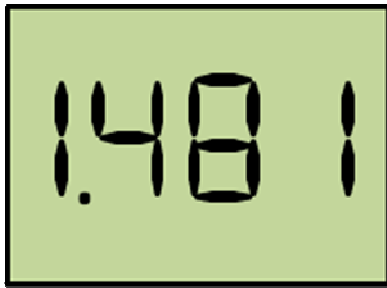
## 5. Device switch ON/OFF



### Switch ON

Keep  button pressed for 2 seconds, device turns on accompanied with an acoustic tone (beep).

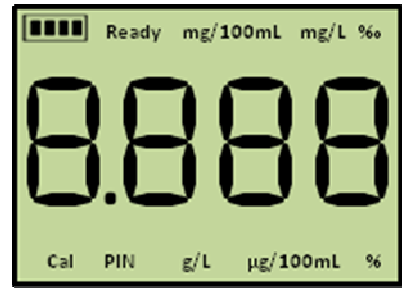
Afterwards a self test of the internal functions and components is automatically performed.



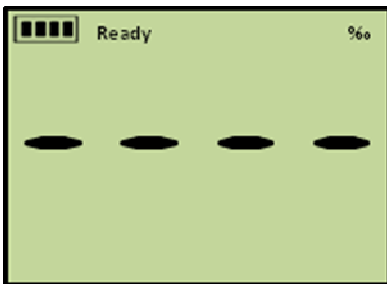
Software-Version



Number of measurements  
till new calibration is required




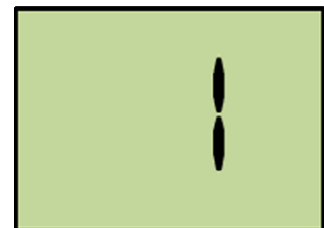
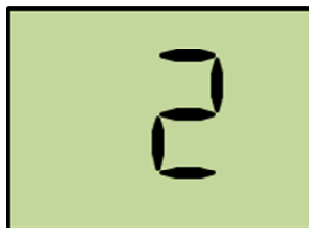
self test



After self-test is completed, the unit is ready for test (Ready).

### Switch OFF

Keep  button pressed, countdown is displayed.  
Device switches off after 3 seconds.



### Automatic switch off

AlcoTrue® E switches off automatically approx. 3 minutes after the last use.



## 6. Carrying out the measurement

### 6.1 Before measuring

#### 6.1.1 Requirements of the person to be tested

- A waiting period of at least 20 minutes shall be observed if the person to be tested has consumed alcohol within the last 20 minutes.

Aromatic drinks (e.g. fruit juice), mouth sprays and mouthwashes containing alcohol, medicines may interfere with the measurement. Rinsing the mouth with non-alcoholic drinks or water does not reduce the waiting period.

- Prior to measuring the person to be tested must breathe normally and calmly. Fast inhaling and exhaling through the mouth should be avoided.
- Tobacco smoke in the expiration air might short the service life time of the alcohol sensor. It must be ensured that the test person has not been smoking before performing the measurement. A waiting period of at least 5 minutes after smoking must be observed.
- A required minimum breath volume must be provided by the person to be tested. The breath flow must be evenly and without interruption.

#### 6.1.2 Conditions



- ***A new mouthpiece must be used for every person to be tested. Risk of contamination!***
- ***Using high grade-alcohol shortly before the measurement will reduce the sensor service life, e.g. mouthwashes containing alcohol.***
- ***The blood alcohol concentration can continue to rise for up to 2h after the cessation of drinking. It should be care taken if a caution result or a result close to the designated blood alcohol concentration is indicated.***
- ***It can take 10h or more for the blood alcohol level to return to zero after a high blood alcohol level has been reached. In such case a further test should be carried out later in the day or the following morning.***

### 6.1.3 Inserting the mouthpiece



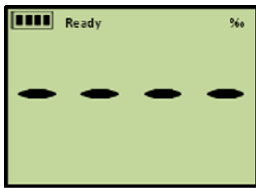
Insert a new mouthpiece into inlet of AlcoTrue® E. Use the hygienic packaging as a hygienic protection.



**Ensure that the mouthpiece packaging is not damaged.**

### 6.2. Breath test procedure

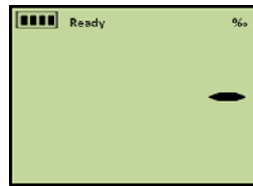
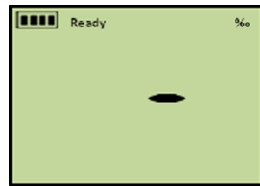
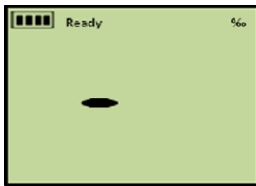
After switching on the AlcoTrue® E and successful self-test, the device is ready for test.



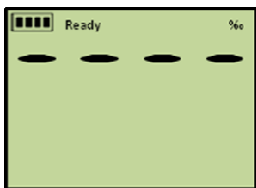
- Wait until device self test is complete and READY displayed.
- Insert mouthpiece into device inlet
- Proceed with the test

the person to be tested must blow evenly through the mouthpiece without interruption. A sufficient flow is indicated by a beep tone.

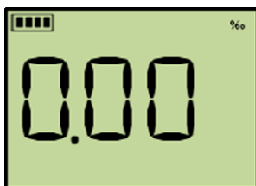
During sampling, the follow display is showing.




Alcohol breath test is successful when breathing volume and blowing time are reached, beep tone stops.



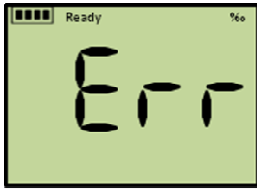
- Wait until analysing complete. Analysing time depends on the measured concentration.



- Test result is displayed.

Press  button for a new measurement.

### 6.3 Error in delivering the breath sample




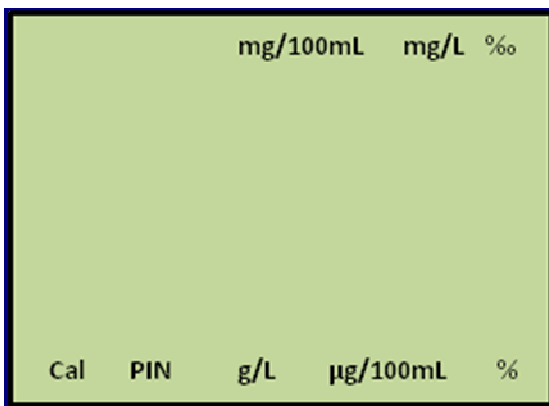
#### Blow failure



This error appears when the person abruptly ceases to exhale or if during the blowing process the respiratory flow drops below the required level before the required volume is reached.

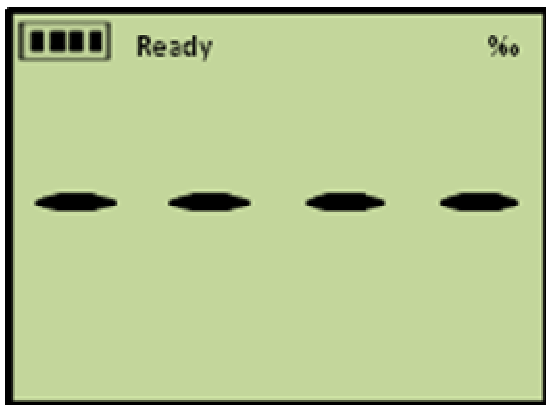
Press  button and repeat the measurement.

## 7. User menu and device settings


Press the  button for 3 seconds until following display will be shown.



The display flashes **Cal**. To scroll through the indicated unit press on the  button. To select a unit press the  button.



selected unit ‰

With the  button you can turn on / off the backlight. Continuous usage of the backlight will reduce battery lifetime.

## 8. Maintenance

### *Cleaning and disinfection*

- Keep Mouthpiece port during the cleaning / disinfection closed.
- Use a soft cloth dampened with a commercial, nonabrasive cleaner to clean the device.
- Use a soft cloth dampened with solution of 70% alcohol in water to disinfecting the device. Lightly wipe the housing surface of the device and then allow to dry in air for at least 30 minutes before turn on device. Otherwise this will short the service life time of the alcohol sensor.



**Do not submerge the device in liquids. Keep the battery compartment closed while cleaning. Battery compartments must remain dry to ensure proper function of AlcoTrue®E.**

### **Calibration**

- The period of calibration validity is 1000 measurements or 12 months, after calibration period expires the device will require re-calibration. Using of AlcoTrue®E with an expired device calibration has a risk of obtaining erroneous results.
- Calibration must be carried out by authorised personnel or bluepoint® MEDICAL GmbH & Co. KG service.

## 9. Disposal of the device



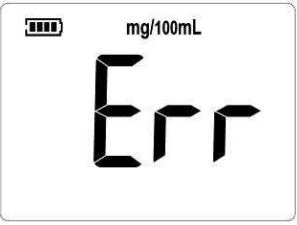
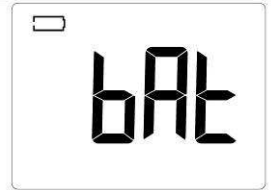
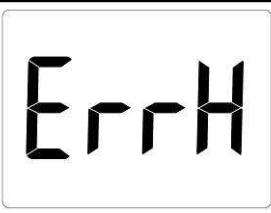
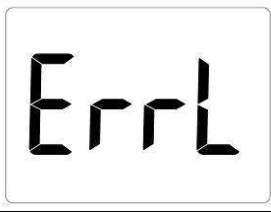
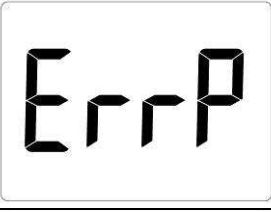
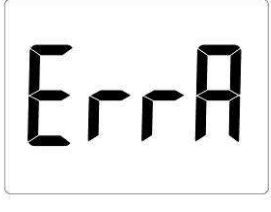

The device should not be disposed with domestic waste. Please ask a suitable contractor to dispose of the instrument and alcohol sensor. The local environmental agency can supply further information.

Empty batteries must be disposed in accordance to the relevant national waste disposal regulations (EU 91/157/EEC).



**Do not open batteries by force and do not expose to fire, danger of explosion!**

## 10. Error / cause - solution

Error message	Cause	Solution
	None sufficient blow volume or breath flow interruption.	Repeat the test. The breath flow must be evenly and without interruption.
	Low battery	Replace the battery
	Ambient temperature is higher than 50°C	Turn off device. Bring device within specified operating conditions. Turn on device.
	Ambient temperature is lower than 5°C	Turn off device. Bring device within specified operating conditions. Turn on device.
	pressure sensor error	Start device again. If the fault occurs again during the self test, runtime or when performing a measurement please contact service.
	Alcohol sensor error due high gradient alcohol into device inlet.	Turn OFF device and wait for at least 5 min. Start device again. If the fault occurs again during the self test, runtime or when performing a measurement please contact service.
	Calibration overdue	device has to be calibrated

## 11. Technical specifications

- **Device name/model/type** AlcoTrue E – breathalyser for personal use
  - **Manufacturer** bluepoint MEDICAL GmbH&Co.KG
  - **Sensor Type** Electrochemical sensor
  - **Sampling system** Standard sampling system by *bluepoint®*
  - **Measurement mode** Active breath test
  - **Measurement range**

Breath alcohol concentration (BrAC)	0.00 to 1,08 mg/L 0 to 108 µg/100mL (Ethanol mass per breath volume at 34°C and 1013 hPa.)
Blood alcohol concentration (BAC)	0.00 to 2,50‰ 0.000 to 0.250 % 0.00 to 2,50g/L 0 to 250 mg/100mL (Ethanol mass per blood volume resp. mass at 20°C and 1013 hPa)
- This data is given using a conversion factor of 2300:1 between blood and breath - alcohol concentrations.
- **Ambient Conditions**

For operation	5°C to 50°C 20 to 98% r.H. (none condensed) 600 to 1400 hPa
For storage	-20°C to 60°C 20 to 98% r.H. (none condensed) 600 to 1400 hPa
  - **Sample conditions**

Minimal acceptable flow	> 12 L/min
Minimal volume	> 1.1L

- **Measurement accuracy**

Reproducibility with an ethanol standard

0 to 0.50 mg/L BrAC                    ≤ 0,024 mg/L

0 to 1,00 ‰ BAC                        ≤ 0,05 ‰

- **Ready for operation**

After switching on                        ca. 6 s

After completing a measurement in range (BrAC):

	Typ.
0,00 mg/L	≤ 2s
0,50 mg/L	≤ 15s

After completing a measurement in range (BAC):

	Typ.
0,00‰	≤ 2s
1,00‰	≤ 15s

- **Mouthpiece type**

Typ „S“ from bluepoint Medical GmbH & Co. KG

- **Calibration interval**                    1000 measurements or 12 months

- **Calibration type**                        Wet gas

Permissible calibration range for unit of measuring value:

mg/L	0.24 to 0.71 mg/L
‰	0.50 to 1.50 ‰
mg/100mL	50 to 150 mg/100mL

Standard calibration value:

mg/L	0.435 mg/L
‰	1.00 ‰
mg/100mL	100 mg/100mL

The use of these standard calibration values corresponds to a conversion factor of 2300:1 between blood and breath alcohol concentration values.

- **Units**  
 Default: mg/L BrAC  
 Available units: µg/100mL BrAC  
                   ‰ BAC  
                   mg/100mL BAC  
                   % BAC  
                   g/L BAC
  
- **Language** English
  
- **Dimensions** 132 mm x 63mm x 26mm
  
- **Weight** approx. 187 g inclusive 3 x 1.5V Alkaline batteries
  
- **Electrical supply**  
 - Internal batteries **3 x 1.5V Type Alkaline**  
 (Mignon, LR6, AA)  
 Typ. ≥ 2000 measurements at room temperature
  
- **Display** 1,8" black/white LCD with LED background light
  
- **Data memory** --
  
- **CE-marking /Standards** EN 61326-1:2006, designed acc EN16280

## 12. Order list

AlcoTrue® E	Reference number
	5040112005
- AlcoTrue®E device - 10 individually packed mouthpieces (S-Type) - 3 x AA Alkaline batteries (LR6, MN1500) - Instruction for use	
Accessories AlcoTrue® E	Reference number
<b>Mouthpiece</b> (S-Typ), 25 hygienic pieces, individually packed	4040121001



## **AlcoTrue® E – Operating instructions**

Version: 2.0 (English)

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