bluepoint MEDICAL

AlcoTrue®P
Instructions for use

Liability

bluepoint MEDICAL GmbH & Co. KG shall not under any circumstances be liable for any direct, indirect, special or consequential damages including without limitation damages for loss of business profits, loss of income, business interruption, loss of business information, loss of use or other related exposures, however caused, arising from an incorrect use of the device not conforming to its intended use or/and if the device is serviced and repaired by personnel not employed or authorized by bluepoint MEDICAL GmbH & Co. KG.

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

AlcoTrue® P 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 24 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 24 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.

Contents

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

Declaration of Conformity

This product meets the requirements of the 2004/108/EG guidelines.

Intended Use

AlcoTrue® P is intended for quick and accurate determination of alcohol concentration in a person's breath. For mobile use with alkaline and rechargeable Li-ion batteries.

Calibration

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

The period of calibration validity is 6 months (standard), after calibration period expires the device will require re-calibration.

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

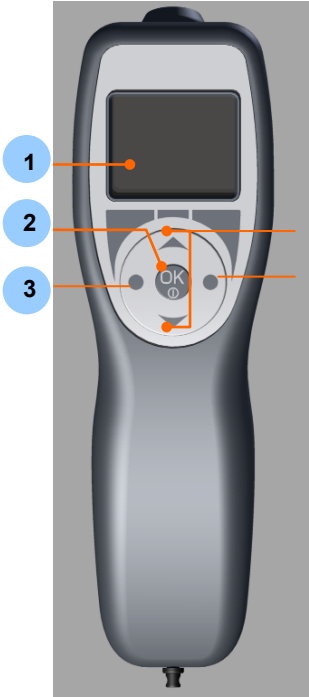The expiry date for calibration is displayed on the "Self test" screen when the device is switched on.

3. Device

3.1 Standard Set

- **AlcoTrue® P device**

- **Mouthpieces (25 pieces individually packed)**

- **Alkaline batteries pack (4x AA, LR6, MN1500)**

- **Alkaline batteries case**

- **User manual**

- **Carrying case, small**

See order list for purchase numbers and accessories.

3.2 AlcoTrue® P device

Pic. 1 (Front view)　　　　Pic. 2 (Side view)　　　　Pic. 3 (Rear view)
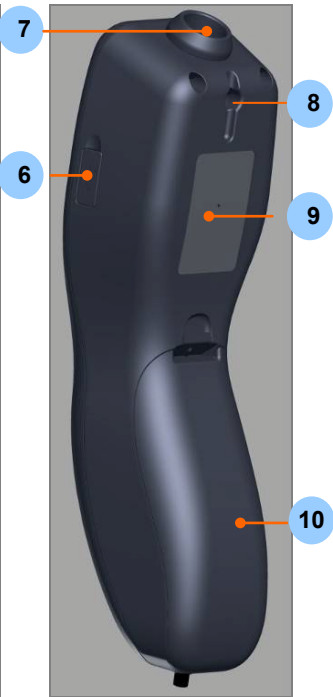
No.	Description	No.	Description
1	Display	6	USB Interface
2	"ON/OFF/Confirm" button	7	Device inlet
3	Back button "Back/Menu"	8	Device outlet
4	Print button (Optional function)	9	Device label
5	Arrow buttons "Up/Down"	10	Battery compartment lid

3.2.1 Device label-symbols

REF	Product/Reference number	**SN**	Serial number
T°C	Operating temperature range	**4x1.5V AA LR6 or 3.7V Li-Poly**	Battery type
DIN EN 15964:2011	Applied standard	**BA1 S XXX**	Type approval METAS, Switzerland
📖ℹ	Consult user manual for detailed operating information!	**IP43**	Protection class (Device with mouthpiece)
C€	The product fulfills the requirements of Directive 2004/108/EG		Disposal instructions

4. Battery information

4.1 Insert/change batteries

Upon initial operation or if the battery symbol on the display indicates "Low Battery":

- Gently press onto the lock of the battery compartment and remove cover. (Pic 4)
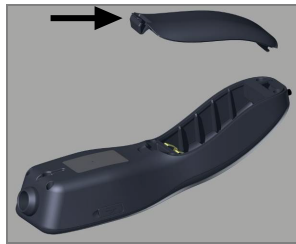
Pic. 4

- Insert batteries in battery case. Observe correct polarity when inserting the batteries! (Pic. 5)

Pic. 5

- Observe the correct position of the batteries' case contacts (upwards) when inserting into the battery compartment. (Pic 6)

Pic. 6

- When using Li-ion battery, observe the correct position of the contacts! (Pic. 7)

Pic. 7

- Close battery cover

Use only 4x 1.5V Type Alkaline (Mignon, LR6, AA) or rechargeable Li-ion batteries type, 3.7V, 2200mAh. Never mix batteries of different brands and/or- 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. (See page 32 for storage temperature information)

The USB port of device can only be connected to computers, which are in accordance with IEC60601-1 or approved according to IEC 90950 and have secure USB ports SELV (Safety Extra Low Voltage).

Use of the USB ports of the device during the measurement is not allowed.

4.2 Battery level indications
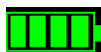
Battery full

75% battery capacity

50% battery capacity

25% battery low

Battery empty
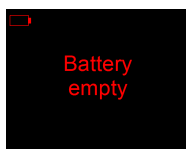
Battery empty

A periodic alarm tone and blinking display message "Battery empty" indicate that the batteries must be changed or charged.
The device automatically switches off after 10 seconds.

4.3 Charging Li-ion battery

The screens below indicate charging of the Li-ion battery. For Li-ion battery charger part number see order list.

Charging process is running.
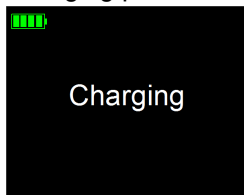
"Battery full" indicates that Li-ion battery is fully charged
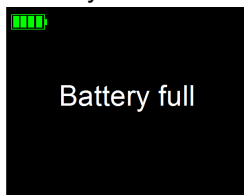
Do not charge the battery outside the temperatures ranges specified, risk of device damages.

5. Device ON/OFF

Switch ON

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

bluepoint M E D I C A L

AlcoTrue P

SW Version 2.4.1A
English
} Software and language versions of the device

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

Device Date/Time

10.05.2017   10:25
Self test

Calibrated until:
05.11.2017
} Calibration Expiry date
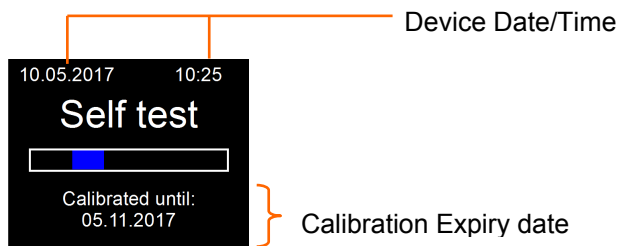
Switch OFF

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

Switch
off in
3 s

Automatic switch off - AlcoTrue® P switches off automatically 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 15 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)-, or 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 they must breathe normally and calmly. Fast inhaling and exhaling through the mouth should be avoided.

- Tobacco smoke in the expiration air might shorten 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 even and without interruption.

Note: Other country specified blow criteria are available upon customer request

6.1.2 Conditions

⚠️

- **A new mouthpiece must be used for every person to be tested. Risk of contamination!**

- **Battery compartment must be closed while using the device.**

- **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 the inlet of AlcoTrue®P- Breathalyser. Please use the hygienic packaging as hygienic protection.


Pic. 8

⚠️ **Please ensure that the mouthpiece packaging has not been open before.**

6.1.4 Alcohol level indication

The AlcoTrue ® P is able to show quantitative and qualitative test results. Additionally, depending from the limits setting, results are displayed in green, yellow and red colours.

Note: Limits can be adjusted or activated only by authorised personnel.

- Quantitative result indications (e.g. Active, Fast modes)

0.00	0.10	0.15	0.25
BrAC mg/L	BrAC mg/L	BrAC mg/L	BrAC mg/L
OK Print	OK Print	OK Print	OK Print
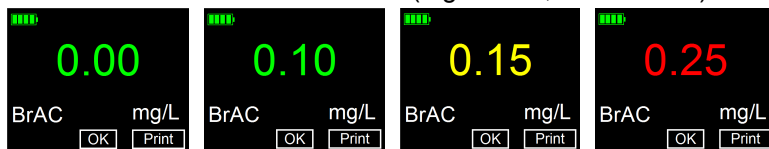
- Qualitative result indications (e.g. Passive, Scanning modes)

No Alcohol	Alcohol
OK Print	OK Print

- The following test results are displayed when "P/A/F" unit is selected. (e.g. Active mode)

Pass	Alert	Fail
OK Print	OK Print	OK Print

Note: **Limits can be adjusted only by authorised personnel.**
Default limits ranges for P/A/F unit are based on ‰ BAC

- 0 to 0.30   P(Pass)
- 0.30 to 0.50   A (Alert)
- ≥ 0.50   F(Fail)

6.2. Measurement modes

After switching on the AlcoTrue ® P and the self-test is successfully performed, the device is ready for alcohol measurement.

The following measurement modes can be selected via user menu:

- Active mode AM
- Fast mode FM
- Passive mode PM
- Scan mode SM
- Mouth alc. mode MA
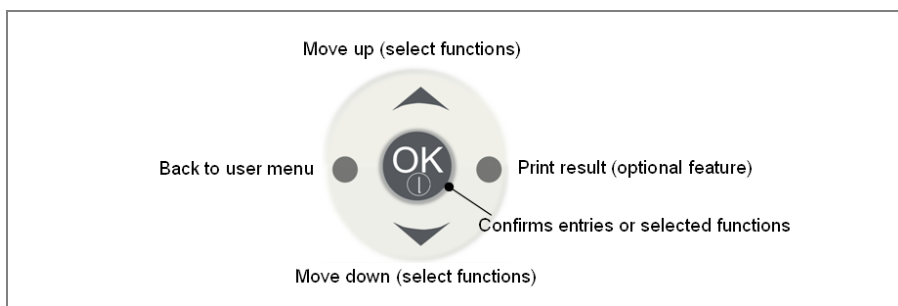
Pic. 9 (Key/Navigation)

Note: Measurement modes available if activated. Only authorised personnel can activate or deactivate the measurement modes.

6.2.1 Active mode AM

To determine the precise alcohol level in the end-expiratory breath of the person to be tested after achieving a minimal breath volume from 1.2 L. It ensures that only deep lung breath (alveolar breath) is analysed.

It is a quantitative measurement of the subject's body alcohol concentration by analysis of deep lung or alveolar breath.
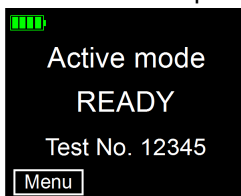

Pic. 10

Test procedure:

Step 1. Turn on device

Step 2. Wait until device self test is complete

Step 3. Insert mouthpiece into device inlet

Step 4. Start measurement
The person must blow evenly through the mouthpiece   without interruption.
A sufficient flow is indicated by a beep tone.

During the test the message "TEST" is displayed and blinks.

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

Step 5. Wait for Analysis - Analyzing time (2 to 25 seconds) depends on the device temperature and the measured concentration.
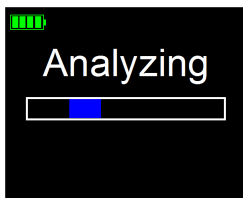
Step 6. Test result is displayed
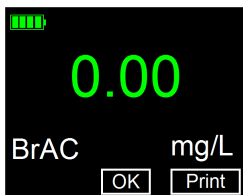
The result is shown with the selected measuring unit. The unit can be selected only by authorised personnel.

Press 🆗 button to set the device in operating mode for a new measurement.

Error in delivering the breath sample

BLOW
FAILURE

OK

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

Press OK button to repeat the measurement.

Warning- Result out of device measurement range specified

≧ 2.62

BrAC   mg/L

OK   Print
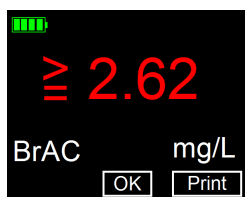
This warning appears when the measurement result over the specified device measurement range.

6.2.2 Fast mode FM (optional)

This mode is intended for persons suffering a COPD, Asthma or reduced lung capacity, which might not be able to provide the required minimum volume (by default 1.2L).

Test procedure:

Step 1. Turn on device

Step 2. Wait until device self test is complete

**Step 3.** Insert mouthpiece into device inlet

Step 4. Select **Fast mode FM** from user menu and press
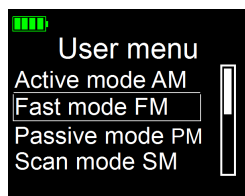
Step 5. Start measurement same as by Active mode

Step 6. Wait for Analysis

Step 7. Test result is displayed

6.2.3 Passive mode PM (optional)

Passive mode measurement is triggered manually by the operator of AlcoTrue® P. To obtain a precise measurement, the sample uptake must be triggered when the person is breathing out. (Pic. 11)
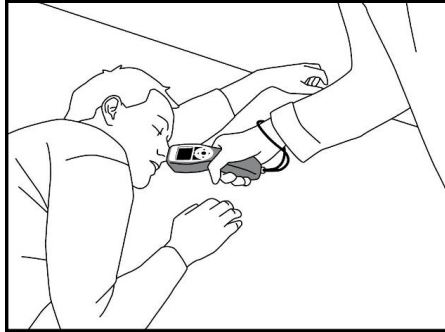
Pic. 11

This measurement mode is suited to determine in a qualitative manner the alcohol concentration of for example: Exhaled air of a person not able to cooperate (e.g. unconscious persons). It is recommended to perform 2 to 3 measurements.

Test procedure:

Step 1. Turn on device

Step 2. Wait until device self test is complete

Step 3. Select **Passive mode PM** from user menu and press OK
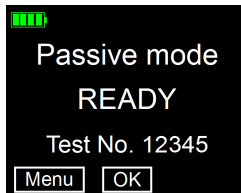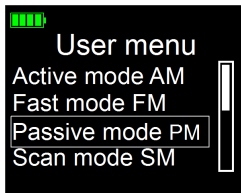
Step 4. Start measurement -Hold the device without a mouthpiece as close as possible in front of the mouth/nose. Press OK button.

During test the message "TEST" is displayed and blinks.

Step 5. Wait for Analysis - Analyzing time (2 to 25 seconds) depends on the device temperature and the measured concentration.

Step 6. Test result is displayed

In passive mode a reasonable measurement result can be obtained during the expiratory plateau (AB), however the best result is obtained at the end of expiration (B). For that reason sampling shall be triggered when the person is breathing out, place the device as close as possible in front of the mouth or nose of the person to be tested.
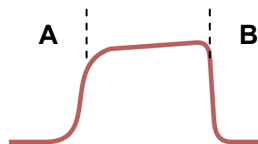
7. Additional/Optional measurement modes

7.1 Scanning mode SM
This is for qualitative identification of alcohol in exhaled air or ambient air.
It is a passive sampling (without mouthpiece) after manual trigger of the sampling by the operator. Possible applications for this function are:

- Qualitative testing of the ambient air alcohol content
- Qualitative determination of alcohol content in exhaled air of a person not able to provide a breath sample (e.g. unconscious persons).
- Qualitative testing of "Non – alcoholic" drinks for alcohol content

Test procedure:

Step 1. Turn on device

Step 2. Wait until device self test is complete

Step 3. Select **Scanning mode SM** from user menu and press

User menu
Active mode AM
Fast mode FM
Passive mode PM
Scan mode SM

Scanning mode
READY
Test No. 12345
Menu   OK
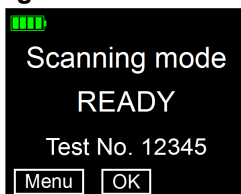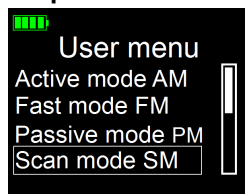
Step 4: Start measurement – Hold the device without a mouthpiece as close as possible to the area to be analyzed. (See Pic.12) and press button.
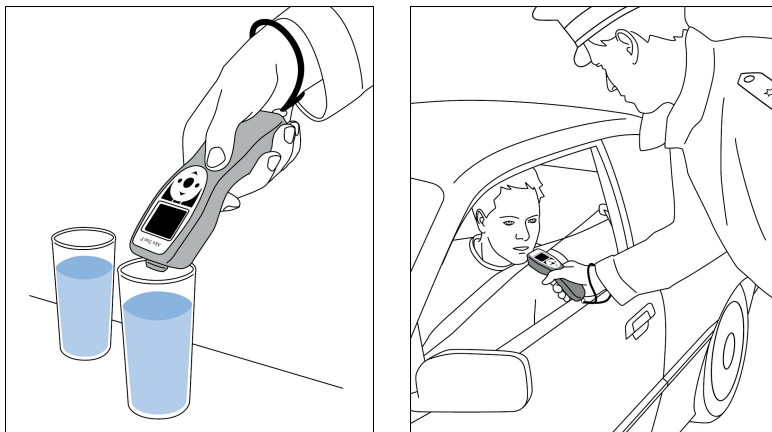
Pic. 12
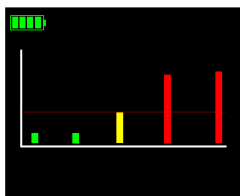
If alcohol is detected, the bars will increase and the colour will change depending on the alcohol content in the air.

Step 6. Test result is displayed. (Possible indications are shown below)

Alcohol detected in gas sample

No alcohol detected

7.2 Mouth alcohol mode MA

This mode is typically used for reasonable suspicion of **mouth alcohol** (Alcohol breath from upper respiratory tract and not alveolar breath)

Mouth alcohol mode consists of two tests with a determined waiting period between the first and second measurement.

Note: The waiting period is set by the manufacturer and can be changed upon request.

Test procedure:

Step 1. Turn on device

Step 2. Wait until device self test is complete

Step 3. Insert mouthpiece into device inlet

Step 4. Select **Mouth alc. MA** from user menu and press
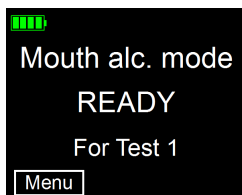
Step 5. Start measurement – The person must blow evenly through the mouthpiece without interruption. A sufficient flow is indicated by a beep tone.
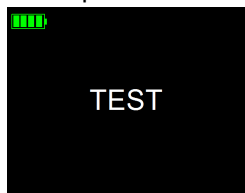
During measurement blinking message "TEST" is displayed

Step 6. Analyzing first measurement
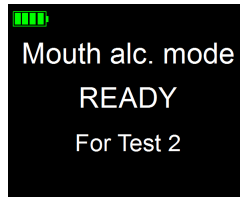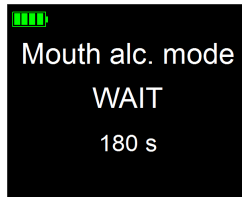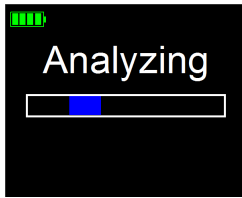
After first measurement, an alloted waiting period must be complete before continuing with the next measurement.

Note: **If after the first analysis mouth alcohol is negative, an alcohol concentration value will be displayed. A second test will be not required.**

Step 7. Start second measurement
Once waiting period has elapsed, the device is automatically READY for the second measurement.
Test person must blow evenly into the mouthpiece without interruption.
A sufficient flow is indicated by a beep tone.

Step 8. Wait for Analysis –
Analyzing time (2 to 25 seconds) depends on the device temperature and the measured concentration.

Step 9. Test result is displayed
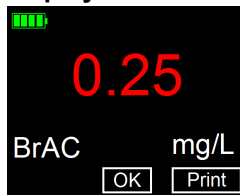
If "Mouth Alcohol" is not found, an alcohol concentration value is displayed.

8. Result indications into device data memory

Each alcohol measurement is automatically stored with date, time, measured value, No. of test and measurement mode used. More than 35 000 measurements can be stored.

Short before data memory full, a warning "> 35 XXX *Tests*" appears every time after device turns on.

A warning "*Data memory full*" appears when device data reached its capacity. Further measurements are not possible. The stored records can be downloaded and archived via PC software. Device memory can be deleted only from an authorised service personal.

Device data memory - Display indications
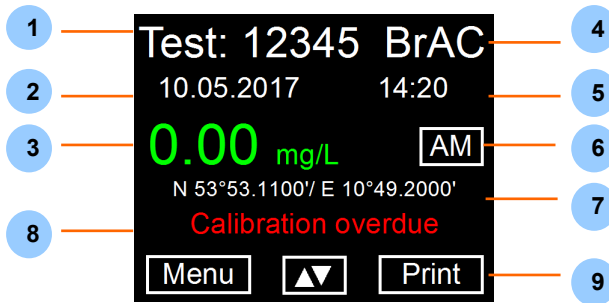
| No.	Description
1	Test Number
2	Date when test was performed
3	Measured alcohol concentration
4	Type of Alcohol concentration (BAC blood alcohol concentration or BrAC breath alcohol concentration)
5	Time when test was performed
6	Type of measurement mode
7	GPS Test location*
8	Calibration status
9	Print option*

*Features available upon request

9. AlcoTrue P – Result printing

The results can be printed using the thermo transfer printer AlcoPrint P from bluepoint MEDICAL.

Note: The printing option of AlcoTrue P can be activated/deactivated only by authorised service personnel.

It is possible to print a test result immediately after a measurement is complete (left screen) or from the "Results" menu (right screen).
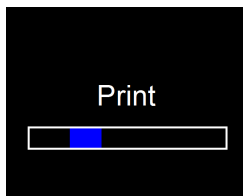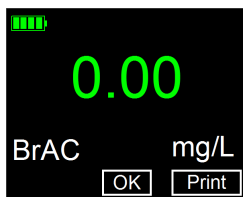
 Indicates printing process

9.1 Default print report

- Date and time of doing the alcohol measurement
- Name of the device with serial number (S/N) and software version (SW)
- Calibration status
- Type of the measurement mode
- Measured test result

9.2 Extended print report

Extended print report includes default print plus selectable points shown below

• Location	• Road
• Name	• Marine
• Age	• Rail
• Gender	• Air
• Weight	• Other
• Date of birth	• GPS coordinates
• ID/Passport Number	• Witness
• Nationality	• Remarks
• License Number	• Police officer
• Issued	

Note: Different report configurations can be printed; however additional information needs to be activated. Only authorised personnel can activate different items for extended print report.

10. Maintenance, cleaning and disinfecting of device

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 disinfect 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 shorten the service life time of the alcohol sensor.

Do not submerge the device in liquids. Liquids must not enter the USB interface. Keep the battery compartment closed while cleaning/disinfecting. Battery contacts and USB interface must remain dry to ensure proper function of AlcoTrue P.

Calibration
- AlcoTrue P calibration interval : 6 months
  acc. MMV941.210, AAMV, EN15964: 2011
- Calibration must be carried out by authorised personnel or bluepoint MEDICAL GmbH & Co. KG service.

11. Disposal of the device

The device should not be disposed of 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!

12. Error, cause, solution

Error	Possible cause	Solution
Error please contact service	Hardware failure	Turn OFF device for 5min. Start device again. If the fault occurs again during the self test, runtime or when performing a measurement please contact service.
Device switches off	- Batteries depleted - Device has been left for 3 minutes without measuring.	Replace batteries
Temperature too high	Device is out of operating temperature range (-10°C to 50°C).	The device must be switched off and brought to within the specified temperature range. Switched on again.
Temperature too low		
AlcoPrint P does not print	- AlcoPrint P is switched OFF - AlcoPrint P Li-ion battery discharged. - Run out of paper	- Switch ON printer - Recharge battery - Insert a new paper roll

Note:
When obviously wrong result, repeat the test or check the calibration.

AlcoTrue P – technical specification

- **Principle of measurement**   long life electrochemical sensor
with high precision   intelligent
microprocessor sampling system

- **Breath sample**   controlled blow volume and time.
Configurable, default 1.2L

- **Measurement modes**   Active mode
Fast mode
Passive mode
Mouth alc. mode
Scanning mode

- **Measurement range**

Breath alcohol concentration   0.00 to 2.60 mg/L
    (BrAC)   (Ethanol mass per breath volume at
$34°C$ and 1013 hPa.)

Blood alcohol concentration   0.00 to 5.50 ‰
    (BAC)   (Ethanol mass per blood volume resp.
mass at $20°C$ and 1013 hPa)

This data is given using a conversion factor of 2100:1 between breath - and blood alcohol concentrations. Other conversion factors are available upon request.

- **Ambient Conditions**

For operation   -10 to 50°C
10 to 100 % R.H. (non-condensed)
600 to 1400 hPa

For storage   -20 to 65°C (-4 to 149°F)
10 to 100 % R.H. (non-condensed)
600 to 1400 hPa

- **Measurement accuracy / Reproducibility with an ethanol standard**

0 to 0.476 mg/L	0.008 mg/L
> 0.476 mg/L to 1mg/L	4 % of measured value
> 1 mg/L	8 % of measured value

0 to 1‰	0.017 ‰
> 1‰ to 2‰	4 % of measured value
> 2 ‰	8% of measured value

- **Sensitivity drift of measured value/month**
  Typically 0.5%

- **Ready for operation** After switching on approximately 6 seconds

- **Applied part (Mouthpiece)** Hygienic mouthpiece (Type "S") with in-build non-return valve and water trap

- **Calibration interval** **6 Months** with automatically reminder

- **Calibration type** Wet gas (default)
  Dry gas
  Flow calibration

- **Result format and unit** digital in green/yellow/red and in **mg/L BrAC** (default)or in ‰ BAC. Other units/ limits can be selected via authorized services.

  Configurable units:

µg/L	g/210L
µg/100mL	µg%
%	g/L
g/100mL	mg/100mL
mg%	mg/mL
P/A/F	P/F
g/kg	P/A/G/F

- **Language** Configurable Multilanguage User menu, **English** (default)

Other available country specific languages e.g. German, French, Spanish, Dutch, Italian, Polish, Serbian can be configured by authorised personnel

- **Dimensions**   185mm x 55mm x 40mm

- **Weight**   approx. 240 g including 4x 1.5v Alkaline batteries
                            approx. 195 g including Li-Poly battery

- **Electrical supply**   Internal batteries:
                            4 x 1.5V Type Alkaline
                            (Mignon, LR6, AA)
                            Typ. ≤ 2100 measurements at room temperature (Using Active mode)
                            Operating temperature -20 to 65°C
                            Storage temperature   -40 to 65°C
                            Or
                            3.7V, 2200mAh Rechargeable Li-Poly type
                            Typ. ≤ 2100 measurements at room temperature(Using Active mode)
                            Charging temperature   0 to 45°C
                            Operating temperature -20 to 60°C
                            Storage temperature   -20 to 60°C

- **Max power consumption   of device by Li-Poly charging**   600mA, 5V DC

- **Device Interface**   **USB**

- **Hardware test procedure**   automatically self-test procedure at device start up

- **Device menu navigation**   5 buttons "map keys" type
                                 Optional: Illuminated keys

- **Warnings information**   **acoustic** and **visual** (configurable)
                                      Different sound and color indications by
                                      negative and   positive measurement
                                      result

- **Device adjustments**   **PIN protected** service menu access

- **Degree of Protection**   **IP 43** (IPX3 protection against
                                      spraying water acc. IEC 60529)

- **Environment condition**   class **M1**
  Mechanical

- **Environment condition**   class **E1**
  Electromagnetic

- **Auto Power OFF**   Configurable, Default: After 3 minutes

- **Display**   **1,77''** colour display

- **Data memory**   **35 000** tests results
                                      with test number, date and time,
                                      calibration status,
                                      GPS test location (optional)

- **CE-marking**   **2004/108/EC**
                                      (EMC electromagnetic compatibility)

- **Standards/Approvals**   **EN15964:2011 – certified by DAKKS
                                      accredited test lab; MMV941.210,
                                      AAMV- Type approved by METAS,
                                      Switzerland (CH-BA1-16003-00);**
                                      EN 55011:2007, EN61326:2006,
                                      IEC 60068-2-6:2007, IEC 60068-2-
                                      27:2008, IEC 60068-2-64:2008,
                                      IEC 68-2-32:1975 +A1/A2:1980,
                                      EN 60529:1991 +A1:2000

Order list

	Order number
Standard Package	4040112012
- AlcoTrue®P Device - 25 individually packed mouthpieces (S-Typ) - 4 x AA Alkaline batteries (LR6, MN1500) - Alkaline batteries case - Instructions for use - Carrying case, small	
Optional	
* Device GPS function * Illuminated keys	4040112019 4040112022
* AlcoPrint P Set	4040112007
- AlcoPrint P Printer - Power supply(EU plug) - AlcoPrint P data cable - Car adapter - Paper roll (1 piece)	

AlcoTrue® P Accessories	**Order number**
Mouthpiece, 25 hygienic pieces, individually packed (S-Typ)	4040121001
Rechargeable Li-Poly battery, 3.7 VDC, 2200 mAh	4040112003
USB Li-Poly battery car adapter	4040112004
Li-Poly battery charger (EU plug), 5 VDC, 600 mA	4040112006
USB cable	1020122057
Alkaline batteries, 4x 1.5v, Mignon, LR6,AA	4040511001
Alkaline batteries case	3040122012
Carrying case, small	4040112005
Carrying case, large	4040112015
Device protective cover/carrying bag	4040112020
Device car holder	4040112021
PC Software including USB data cable	4040112017
Instructions for use AlcoTrue P	4040112014

AlcoPrint P Accessories	**Order number**
- Power supply(EU plug)	4040112009
- Car adapter	3040122004
- AlcoPrint P data cable	3040122011
- Paper roll (5 pieces)	1040122100

AlcoTrue® P instructions for use
Version: **EN**
The information in this document is subject to alterations without notice.