

AlcoTrue[®]M

Instructions for Use

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

2. 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.

3. Intended use and medical purpose of the AlcoTrue M

Intended Use:

The AlcoTrue M is a handheld medical breathalyzer with internal batteries intended for quick and accurate determination of the alcohol concentration in the exhaled breath of patients with clinical suspicion of alcohol intoxication.

Measurement principle: Electrochemical sensor

Intended medical indications:

Measurement of breath alcohol of a patient when there are concerns regarding blood alcohol level or alcohol consumption, for example in: emergency medicine, psychiatry, addiction clinics or at a methadone maintenance clinic to avoid side effects.

Intended user profile:

Healthcare professional personal with competence in the breath alcohol measuring procedure and interpretation of the measurement results.

Intended patient groups:

Teens, young adults, adults

Clinical environment:

Professional healthcare facility

Contraindications:

Not intended to be used in presence of oxygen enriched environments or flammable anaesthetic mixtures.

Manufacturer:

bluepoint MEDICAL GmbH & Co. KG

An der Trave 15

23923 Selmsdorf, Germany

Phone: +49 (38823) 5488 – 0

Fax: +49 (38823) 5488 – 29

E-Mail: info@bluepoint-medical.com







Web: www.bluepoint-medical.com





4. General warnings and safety notices

General warnings	
WARNING:	Do not use the AlcoTrue M if it appears or is suspected of being damaged. Damage to the device may result in degraded performance.
WARNING:	Do not use this equipment if the calibration period has expired.
WARNING:	A new mouthpiece must be used for every person to be tested. Risk of cross contamination!
WARNING:	No modification of this equipment is allowed.
WARNING:	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
WARNING:	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and therefore result in improper operation.
WARNING:	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AlcoTrue M, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
WARNING:	Devices can only be connected to the USB port of the AlcoTrue M, which are in accordance with IEC 60601-1 or approved according to IEC 90950 and having secure to the USB ports SELV (Safety Extra Low Voltage).
WARNING:	Do not use the USB port of the device during measurements.

General safety notices

	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.
	Only use the specified accessories and consumables in the order list.
	Calibration, adjustment and maintenance work must be carried out by authorised service personal only.
	For repairs only use original parts from bluepoint MEDICAL GmbH & Co.KG.
	<p>Any serious incidents that have occurred in relation to this equipment should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. To report patient safety related events, send an email to the following manufacturer's address: prrc@bluepoint-medical.com with at least following information:</p> <ul style="list-style-type: none"> - order number and product name - serial number / batch number of the product - date of the serious incident - description of the serious incident affecting the patient or any injuries - your contact data (institution, address, contact person/representation, title and telephone number)

Safety symbols used in this document:

	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

5. Description of the medical device

AlcoTrue M – device overview



1. Applied part – S-Mouthpiece
2. Device inlet
3. Device outlet
4. Display
5. Keypad
6. ON/OFF/Confirmation
7. USB port
8. Device label
9. Battery compartment



Side view

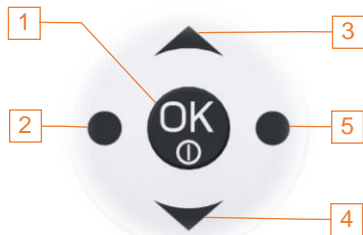


Front view



Rear view

AlcoTrue M – Keypad



1. ON/OFF/ Entry confirmation
2. Menu/Return (back to user menu)
3. Move Up (select functions)
4. Move Down (select functions)
5. Print result (optional function)

AlcoTrue M – Set overview



1. AlcoTrue M - Device
2. 4 x 1.5V AA Alkaline batteries
3. Alkaline battery case
4. Instructions for use
5. 25 individually packed S-Mouthpieces
6. Carrying case (small)

AlcoTrue M – Pictures of the application and device operating positions



Active measurement modes
(Active mode, Fast mode, Mouth alc. mode)



Passive measurement modes without
mouthpiece
(Passive mode, Scanning mode)

6. Battery Information

The device's batteries need to be inserted upon the initial operation or changed when the battery symbol on the display indicates "Battery empty".

AlcoTrue M – Battery compartment



1. Battery contact „-“
2. Battery contact „+“
3. Battery type detection
4. Sealing ring
5. Device sealing

Battery compartment - cover remove

Battery compartment - Overview

AlcoTrue M – overview of battery type



Alkaline batteries (4 x1.5V AA LR6)



Use only 4 x 1.5V Type Alkaline (Mignon, LR6, AA)

Do **not** use NiMH, NiCd or similar rechargeable batteries with this equipment. Risk of device damages!



Battery compartment must be closed whilst using the device.

AlcoTrue M - Insert/change of the 4 x 1,5V AA Alkaline batteries

1



2



3



4



Observe correct polarity when inserting the 4 x 1.5V AA LR6 alkaline batteries into the battery case!



Observe the correct position of the battery case contacts (upwards) when inserting into the battery compartment!



Never mix AA batteries of different brands and different discharge levels! Always replace all 4 x 1.5V AA batteries at the same time.


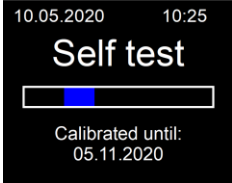
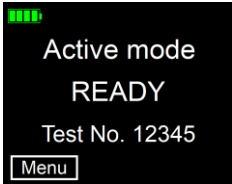




Remove the AA batteries if the device is to be stored or not used for a long period of time. Risk of device damage due to leaking battery acid.












Do not recharge alkaline batteries. Risk of damage to the device!

7. Device switch ON/OFF procedure

	<p>Switch ON Keep "OK" button pressed for 2 seconds, device switches on accompanied by an acoustic tone (beep).</p>
	<p>Afterwards a self-test of the internal functions and components is automatically performed.</p>
	<p>After a successful self-test, the device automatically switches to active mode and it is ready for use.</p>
	<p>Switch OFF Keep "OK" button pressed, countdown is displayed. Device switches off after 3 seconds.</p>
	<p>Automatic switch off AlcoTrue M switches off automatically 3 minutes after the last use.</p>

8. Requirements and safety notices prior to conducting measurements

	<p>A new mouthpiece must be used for every person to be tested. Risk of cross contamination!</p>
	<p>Consuming high proof alcohol just before the measurement will reduce the sensor's service life (e.g. mouthwashes containing alcohol)</p>
	<p>A waiting period of at least 15 minutes should be observed if the person to be tested has consumed alcohol within the last 20 minutes.</p>
	<p>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.</p>
	<p>Tobacco smoke in expired air might shorten the service life time of the alcohol sensor. Ensure that the person to be tested has not been smoking prior to performing the measurement. A waiting period of at least 5 minutes after smoking must be observed.</p>
	<p>Prior to carrying out a measurement, the person to be tested should breathe normally and calmly. Rapid inhalation and exhalation through the mouth should be avoided.</p>
	<p>The person to be tested must provide a required minimum breath volume of 1.2L. The breath flow must be even and without interruption.</p>
	<p>The blood alcohol concentration can continue to rise for up to 2hrs after the cessation of drinking. Care should be taken if a caution result or a result close to the designated blood alcohol concentration is indicated.</p>
	<p>It can take 10hrs or more for the blood alcohol level to return to zero after a high blood alcohol level has been reached. In such a case further tests should be carried out later that day or the following morning.</p>

9. Handling of the mouthpiece (applied part)

S-Mouthpiece is a hygienically wrapped part with built in non-return valve. It is intended for single use when fitted to the medical breathalyzer AlcoTrue M and through which the subject under test provides the breath specimen. It protects the person under test from inhaling contaminated air from previous usage of the device. It is an applied part **Type B** for the medical breathalyzer AlcoTrue M.

Inserting the mouthpiece



Insert a new mouthpiece into the inlet of AlcoTrue M breathalyzer.



Do not use the mouthpiece if its packaging has been previously opened.
Risk of cross contamination!



Use the hygienic packaging as hygienic protection around the mouth contact area whilst inserting the mouthpiece into the device inlet.

10. Breath test – Active measurement mode

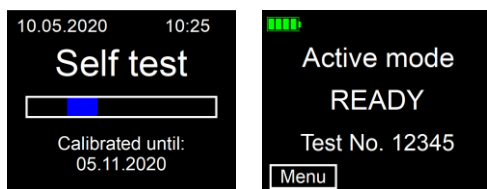
The active measurement mode (AM) is adopted for determining the precise alcohol level in the *end-expiratory breath*¹⁾ of the person to be tested, after achieving a minimal breath volume of 1.2 L. It ensures that only deep lung breath "*alveolar air*"²⁾ is analyzed.

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

Active mode test procedure:

Step 1: Switch the device ON

Step 2: Wait until the device self-test has finished and the device shows "READY"



Step 3: Insert mouthpiece into the device inlet

Step 4: Start measurement

The person to be tested must blow evenly through the mouthpiece without interruption, for as long as possible. A sufficient flow is indicated by a beep sound.



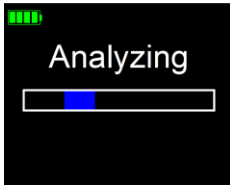
During the test the message, "TEST" is displayed and blinks.

Alcohol measurement is successful when breathing volume and blowing time are reached - beep sound stops and indicates the end of the measurement.

- | | |
|---------------------------|--|
| 1) end-expiratory breath: | air considered sufficiently representative of alveolar air |
| 2) alveolar air: | air contained in the pulmonary alveoli where the gaseous exchange takes place between the blood and the gas contained within the alveoli |

Step 5: Wait for analysis

Analyzing time (2 to 25 seconds) depends on the temperature of the device and the measured concentration.



Step 6: Test result is displayed



The measurement result is shown in pre-selected unit mg/L BrAC (milligram of ethanol per liter of exhaled breath). The test result can be printed, via the optional mobile printer (see ordering information)





When there is obviously an incorrect result, repeat the test or check the calibration.

Step 7: Remove the mouthpiece from device and dispose of it as infectious waste.

Step 8: Press "OK" button to set the device to operating mode for a new measurement or press and hold the "OK" button to switch the device OFF.

11. Other measurement modes

	The additional measurement modes can be activated by authorised services only.
	In some countries, passive measurements are not allowed. The hospital as well as local and governmental regulations have to be considered.

11.1 Fast mode FM (optional)

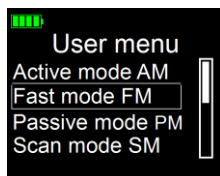
This mode is intended for persons suffering from medical conditions such as a COPD, asthma or reduced lung capacity, who might not be able to provide the required minimum volume (by default: 1.2L).

Fast mode test procedure:

Step 1: Switch the device ON

Step 2: Wait until the device self-test has finished

Step 3: Select Fast mode FM from user menu and press „OK“



Step 4: Insert mouthpiece into the device inlet

Step 5: Start measurement analogous to active mode

Step 6: Wait for analysis

Step 7: Test result is displayed

Step 8: Remove the mouthpiece from the device and dispose of it as infectious waste.

Step 9: Press “OK” button to set the device to operating mode for a new measurement or press and hold the” OK” button to switch the device OFF.

11.2 Passive mode PM (optional)

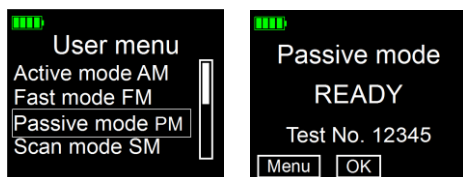
Passive mode measurement is triggered manually by the operator of the device. This measurement mode is suited to determine the alcohol concentration in a qualitative manner in special cases such as: exhaled air of a person not able to cooperate (e.g. unconscious person). It is recommended to perform 2 to 3 measurements.

Passive mode test procedure:

Step 1: Switch the device ON

Step 2: Wait until device self-test has finished

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 (**2 cm to 5 cm**) in front of the mouth/nose of the person to be tested. Press “OK” button. The device **must not** touch the patient to be tested! **Risk of cross contamination!**

During a test the message, “TEST” is displayed and flashes.

Step 5: Wait for analysis

Analyzing time (2 to 25 seconds) depends on the temperature of the device and the measured concentration.

Step 6: Test result is displayed



Step 7: Press “OK” button to set the device to operating mode for a new measurement or press and hold the “OK” button to switch the device OFF.

11.3 Scanning mode SM (optional)

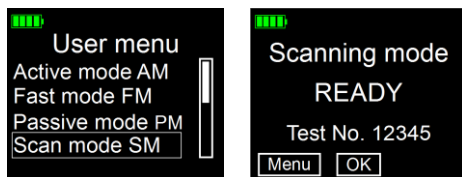
The scanning mode is a more sensitive passive sampling method (without mouthpiece) triggered manually by the operator. This measurement mode is suited to determine the alcohol concentration in a qualitative manner in special cases such as: exhaled air of a person not able to cooperate (e.g. unconscious persons).

Scanning mode test procedure:

Step 1: Switch the device ON

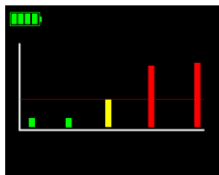
Step 2: Wait until the device self-test has finished

Step 3: Select Scanning mode SM from user menu and press "OK"



Step 4: Start measurement

Hold the device **without a mouthpiece** as close as possible (**2 cm to 5 cm**) in front of the mouth/nose of the person to be tested. Press "OK" button. The device **must not** touch the patient to be tested! **Risk of cross contamination!**



If alcohol is detected, the bars will increase in size and the colour will change depending on the pre-configured alcohol limits.

Step 5: Test result is displayed.

"Alcohol" if alcohol detected or "No Alcohol" if no alcohol detected

Step 6: Press "OK" button to set the device to operating mode for a new measurement or press and hold the "OK" button to switch the device OFF.

11.4 Mouth alcohol mode MA (optional)

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

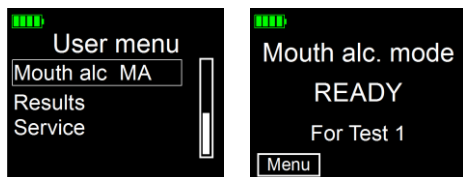
Mouth alcohol mode consists of two tests with a determined waiting period between the first and second measurement.

Mouth alcohol mode - test procedure:

Step 1: Switch the device ON

Step 2: Wait until the device self-test has finished

Step 3: Select Mouth alc. MA from user menu and press „OK“



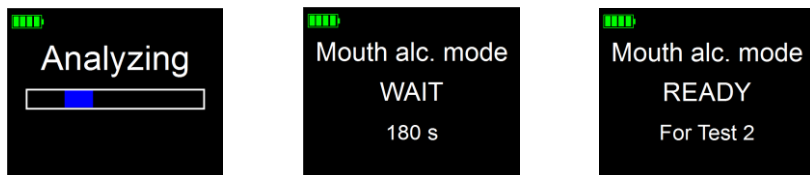
Step 4: Insert mouthpiece into the device inlet

Step 5: Start measurement analogous to active mode

The person has to blow evenly through the mouthpiece without interruptions. A sufficient flow is indicated by a beep sound.

During the measurement the flashing message “TEST” is displayed.

Step 6: Analyzing first measurement



After first measurement, an allotted waiting period must be observed before continuing with the next measurement.

Note: If after the first analysis mouth alcohol is negative, an alcohol concentration value will be displayed. In this case a second test will not be required.

Step 7: Start second measurement

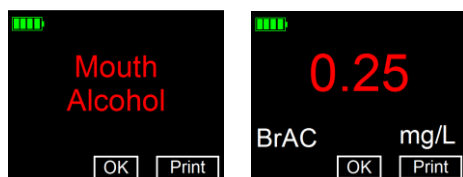
Once the waiting period has elapsed, the device is automatically READY for the second measurement.

The person under test 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 detected, the alcohol concentration value is displayed.

Step 10: Remove the mouthpiece from the device and dispose of it as infectious waste.

Step 11: Press “OK” button to set the device to operating mode for a new measurement or press and hold the “OK” button to switch the device OFF.

12. Device data memory

Each alcohol measurement is automatically stored with date, time, measured value, number of test and measurement mode used. More than 35 000 measurements can be stored. Just before the data memory reaches its capacity limit a warning “> 35 XXX Tests” appears every time the device is turned on. The warning message “Data memory full” appears when the device reaches its storage capacity. Further measurements are not possible. The stored records can be downloaded and archived via PC software. Optional and depending of the configuration the results can be printed using the mobile printer AlcoPrint P.



Device memory can only be deleted by authorized service personal.





13. Troubleshooting Messages, Cause, Remedy

System messages		
Message	Cause	Remedy
"Calibration overdue"	The calibration interval has expired	Send device to authorized services for calibration
"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. Switch on again.
"Temperature too low"		
"≥ 2.62 mg/L BrAC"	The measurement result exceeds the device's specified measurement range. Excessive concentration detected.	A waiting period of at least 15 minutes should be observed if the person to be tested has consumed alcohol within the last 20 minutes.
"≥ 5.50 ‰ BAC"		
" ≥ x.xx unit "		
">35 000 Tests"	Data memory nearly full (< 500 tests records)	Backup the stored data and delete the data memory (authorized service only)
"Data memory full"	--	Backup the stored data and delete the data memory (authorized service only)
"Battery empty"	AA batteries depleted	Replace all 4 x 1.5V AA batteries

Errors and Faults messages		
Message	Cause	Remedy
Device cannot be switched ON	AA batteries depleted, or HW failure	Replace all 4 x 1.5V AA batteries
"Error 01 please contact service"	HW Failure Alcohol sensor saturated due to excessive alcohol concentration in ambient air.	Switch OFF the device for 30 minutes. Switch ON the device. If the fault occurs again during the self-test runtime, please contact service.
"Error 02 please contact service"	HW Failure Pressure sensor	Switch OFF/ON the device. If the fault occurs again during the self-test runtime, please contact service.
"Error 04 please contact service"	HW Failure RTC, Internal backup battery	Replace backup battery (authorized services only)
"Error 08 please contact service"	HW Failure Pump	Switch OFF/ON the device. If the fault occurs again during the self-test runtime, please contact service.
"Error 16 please contact service"	HW Failure Data memory	Backup the stored data and delete the data memory (authorized service only)
"Blow failure"	The person abruptly stops exhaling, or if during the blowing process, the respiratory flow drops below the required level before the required volume is reached	The person must blow evenly through the mouthpiece without interruption, for as long as possible.
"Test failure / Redo the test"	System failure during the measurement procedure	Switch OFF/ON the device and repeat the test


14. Cleaning and disinfection of the medical device

Cleaning and disinfection of device should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

	AlcoTrue M device cannot be autoclaved or sterilized! Machine cleaning of device is not allowed! Cleaning of device by ultrasound is not allowed! Thermal disinfection of device is not allowed!
	Do not submerge the device in liquids, this avoids any damage or defects due to liquids entering/ soaking into the USB port or other gaps. Keep the battery compartment closed whilst cleaning, disinfecting. Battery contacts and USB port must remain dry to ensure proper function of the device.
	Keep mouthpiece nozzle (device inlet) and device outlet covered during cleaning/ disinfection.
	Keep device switched OFF during cleaning and disinfection procedure. Risk of damage to the device!

Manual cleaning and disinfection of the device:


Use a soft cloth moistened with a 70% certified isopropyl alcohol to clean and disinfect the device.

	Lightly wipe the housing surface of the device and then allow to dry in air for at least 30 minutes before switching on the device. Acting contrary to this may shorten the service life of the alcohol sensor.
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Inspect the device after cleaning/disinfection procedure:

If damages to the device (e.g. discolouration, cracks, and deformation of plastic parts) or faulty operation is detected, then send it for repair to bluepoint MEDICAL GmbH&Co.KG or an authorized service centre.

Storage and transport of device:

	It is recommended to store the device under normal environmental conditions. Store the device in the dedicated equipment carrying case to protect it from dust, heat and moisture
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15. Maintenance and calibration





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

The calibration validity period is 6 months. Upon expiry of the calibration period, the device will require a re-calibration.











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






The expiration date for calibration is displayed on the “Self-test” screen when the device is switched on.

16. Disposal of the medical device and parts













 	<p>The device should not be disposed of in domestic waste. Please ask a suitable contractor to dispose of the instrument The local environmental agency can supply further information.</p> <p>Depleted batteries must be disposed of in accordance to the relevant national waste disposal regulations.</p>
	<p>The mouthpieces must be disposed of as infectious waste.</p>
	<p>Do not open batteries by force and do not expose to fire, danger of explosion!</p>






17.Explanation of device markings and symbols

AlcoTrue M – marking and symbols explanation	
	Catalogue number
	Serial number
	Consult instructions for use
	Unique Device Identifier
	Medical device
	Applied Part class per IEC 60601-1: Type B (not defibrillation proof)
IP53	Protection class against harmful ingress of water and particulate matter. (Device with mouthpiece installed and in operating position)
	CE-European Conformity authorization mark. 0482-notified body
	Date of manufacture
	Manufacturer
	Do not dispose of in with domestic waste

	Keep away from heat and sunlight
	Keep dry
	Temperature limits to which the medical device can be safely exposed.
	Range of humidity to which the medical device can be safely exposed.
	Range of atmospheric pressure to which the medical device can be safely exposed.

Mouthpieces (Applied Part) - marking and symbols explanation

	Catalogue number
	Batch code
	Unique Device Identifier
	Medical device
	Date of manufacture
	Manufacturer
	CE-European Conformity authorization mark.
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Non-sterile
	Does not contain Phtalates
	Does not contain Latex

	Keep away from heat and sunlight
	Temperature limits to which the medical device can be safely exposed.
	Range of humidity to which the medical device can be safely exposed.
	Range of atmospheric pressure to which the medical device can be safely exposed.
	Number of units

18. Technical specification

Measurement principle	Electrochemical sensor (fuel cell technology)
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Measurement modes	Configurable, Active mode (default)
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Breath sample	Configurable, Breath volume >1.2L (default)
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Measurement result indication	
Format	Digital
Unit	Configurable, mg/L BrAC (default)
Colour coded	Configurable, Default: Green <0.14 mg/L; Yellow <0.24 mg/L; Red ≥0.24 mg/L

Device language	Configurable, German (default)
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Measurement range	
Breath alcohol concentration (BrAC)	0.00 to 2.60 mg/L (mass of ethanol per breath volume at 34°C and 1013 hPa)
Blood alcohol concentration (BAC)	0.00 to 5.50 ‰ (Ethanol mass per blood volume resp. mass at 20°C and 1013 hPa)
BrAC / BAC conversion factor	Configurable, 2100:1 (default)

Measurement accuracy / reproducibility with an ethanol standard solution	
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

Measurement accuracy acc. DIN EN 15964	
0 to 0.20 mg/L	±0.02 mg/L
> 0.20 mg/L	±10 % of measured value

Calibration of medical device	
Calibration interval	6 Months
Calibration type	Wet gas, Dry gas, Flow calibration

Ready for operation	Approximately 6 seconds after switching on. (including self-test procedure)
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Classification of medical equipment per Medical Device Directive 93/42/EEC, Annex IX and Medical Device Regulation (MDR) 2017/745, Annex VIII	
AlcoTrue M – device	Class Im (device with a measuring function)
Mouthpiece	Class I

Classification of medical equipment per IEC 60601-1	
Protection against electric shock	Class II, Type B (not defibrillation proof)
Supply connection	Internally powered
Protection against harmful ingress of water and particulate matter, IEC 60529	IP53 (Device with mouthpiece installed and in operating position)
Mode of operation	Continuous operation

Applied part Type B	Disposable mouthpiece (Type “S”) with built in non-return valve and water trap. Maximal operating temperature <41°C
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Electrical supply	
Internal batteries	4 x 1.5V Type Alkaline (Mignon, LR6, AA)

Device interface	USB
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Environmental conditions		
During operation	Temperature	-10°C to 50°C
	Relative Humidity	10% to 100% R.H. (non-condensing)
	Ambient pressure	800hPa to 1060hPa
During transport and storage	Temperature	-20°C to 65°C
	Relative Humidity	10% to 100% R.H. (non-condensing)
	Ambient pressure	800hPa to 1060hPa

Physical characteristics of AlcoTrue M - device	
Dimensions	185mm x 55mm x 40mm
Weight	Approx. 240g including Alkaline batteries

Physical characteristics of AlcoTrue M - Set	
Dimensions	230mm x 200mm x 85mm
Weight	Approx. 820g

UMDNS-code	17-475
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DIMDI registration number	DE/CA81/25012019T02
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CE-Marking	93/42/EEC (Medical device directive)
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Standards and Approvals	
IEC 60601-1:2005/AMD2:2020	
IEC 60601-1-2:2014	
DIN EN 15964:2011	

19. Ordering information

AlcoTrue M - Set	UDI number	Order number
<ul style="list-style-type: none"> • AlcoTrue M – Device • 4 x 1.5V AA Alkaline batteries (LR6, MN 1500) • Alkaline battery case • 25 individually packed mouthpieces (S-Type) • Instructions for Use • Carrying case, small 	5 42516796 0177 2	5040112002

AlcoTrue M - Applied part	UDI number	Order number
25 individually packed mouthpieces (S-Type)	2 42516796 0155 9	4040121001

AlcoTrue M - Accessories and consumables	Order number
Alkaline battery case	3040122012
Alkaline batteries, 4 x 1.5V, Mignon, LR6, AA	4040511001
Carrying case, small	4040112005
Carrying case, large	4040112015
PC Software including USB data cable	4040112017
Instructions for use AlcoTrue M - EN	6040112000

AlcoPrint P - Mobile printer Set	Order number
<ul style="list-style-type: none"> • AlcoPrint P – Printer • Power supply (EU Plug) • AlcoPrint P data cable • Paper roll (1 piece) 	4040112007

AlcoPrint P - consumables	Order number
Paper roll (5 pieces)	1040122100

AlcoTrue M - Instructions for Use

Language version: English

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bluepoint MEDICAL GmbH & Co.KG

An der Trave 15
23923 Selmsdorf
Germany

Phone: +49 (38823) 5488-0

Fax: +49 (38823) 5488-29

E-Mail: info@bluepoint-medical.com

Web: www.bluepoint-medical.com



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